Home Health Agencies (HHAs)

2180 - HHA – Citations and Description
(Rev. 1, 05-21-04)

2180A - Citations
(Rev. 1, 05-21-04)

The statutory authority for applying CoPs to HHAs is found in §§1861(o) and 1891 of the Act. The regulations are found in 42 CFR Part 484. Appendix B contains Interpretive Guidelines for surveyors.

2180B - Types of Agencies
(Rev. 1, 05-21-04)

An HHA may be a public, nonprofit or proprietary agency or a subdivision of such an agency or organization.

1. Public agency is an agency operated by a State or local government. Examples include State-operated HHAs and county hospitals. For regulatory purposes, "public" means "governmental."

2. Nonprofit agency is a private (i.e., nongovernmental) agency exempt from Federal income taxation under §501 of the Internal Revenue Code of 1954. These HHAs are often supported, in part, by private contributions or other philanthropic sources, such as foundations. Examples include the nonprofit visiting nurse associations and Easter seal societies, as well as nonprofit hospitals.

3. Proprietary agency is a private, profit-making agency or profit-making hospital.

2180C - General Requirements
(Rev. 1, 05-21-04)

Section 1861(o) of the Act defines an HHA as an agency or organization which:

- Is primarily engaged in providing skilled nursing services and other therapeutic services;

- Has policies established by a group of professionals (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services which it provides;

- Provides for supervision of above-mentioned services by a physician or registered professional nurse;

- Maintains clinical records on all patients;

- Is licensed pursuant to State or local law, or has approval as meeting the standards established for licensing by the State or locality;

- Has in effect an overall plan and budget for institutional planning;

- Meets the CoPs in the interest of the health and safety of individuals who are furnished services by the HHA; and

- Meets additional requirements as the Secretary finds necessary for the effective and efficient operation of the program.

For purposes of Part A home health services under Title XVIII, the term "home health agency" does not include any agency or organization which is primarily for the care and treatment of mental diseases.

The CoPs for a Medicare-approved HHA found in 42 CFR Part 484 are also based on §1891 of the Act. These CoPs are listed in Appendix B, Interpretive Guidelines for HHAs. Section 1891 of the Act requires, among other things, that the HHA:

- Protect and promote the rights of each individual under its care;

- Disclose ownership and management information required under the Act;

- Not use as a home health aide (on a full-time, temporary, per diem, or other basis) any individual to provide items and services described in §1861(m) of the Act, unless the individual has completed a training and competency evaluation program (CEP) or a CEP that meets minimum standards established by the Secretary, and is competent to provide such items and services;

- Operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of §1124 of the Act);

- Operate and provide services in compliance with accepted professional standards and principles which apply to professionals providing items and services for the HHA;

- Include an individual's plan of care (PoC) required under §1861(m) of the Act as part of the clinical record described in §1861(o)(3) of the Act; and

- Comply with the requirements of §1866(f) of the Act relating to maintaining written policies and procedures respecting advance directives.

2180D - Services Provided
(Rev. 1, 05-21-04)

All HHAs must provide skilled nursing services and at least one of the following other therapeutic services: physical therapy, speech language pathology, or occupational therapy, medical social services, or home health aide services in a place of residence used as a patient's home. The HHA must provide at least one of these services (i.e., skilled nursing, physical therapy, speech language pathology, occupational therapy, medical social services, or home health aide services) directly and in its entirety by employees of the HHA. The other therapeutic service and any additional services may be provided either directly or under arrangement.

An HHA is considered to provide a service "directly" when the person providing the service for the HHA is an HHA employee. For the purpose of meeting 42 CFR Part 484.14(a), an individual who works for the HHA on an hourly or per visit basis may be considered an agency employee if the HHA is required to issue a Form W-2 on his/her behalf.

An HHA is considered to provide a service "under arrangements" when the HHA provides the service through contractual or affiliation arrangements with other agencies or organizations, or with an individual(s) who is not an HHA employee. The HHA is responsible for ensuring that the applicable CoPs are complied with, as though the HHA was furnishing the services directly.

When hourly or per visit contracts are used, or when services are provided under arrangements, there must be a written agreement or contract between such personnel, or this agency or organization, and the HHA which specifies:

- Patients are accepted for care only by the primary HHA;
- The services to be furnished under the contract or agreement;
- The necessity to conform to all applicable agency policies, including personnel qualifications;
- The responsibility for participating in developing plans of care;
- The manner in which services will be controlled, coordinated, and evaluated by the primary HHA;
- The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation; and
- The procedures for payment for services furnished under the agreement or contract.

2180E – Application of Home Health Agency Conditions of Participation to Patients Receiving Chore Services Exclusively

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

In addition to the home health services listed in §1861(m) of the Act, and Medicaid State Plan services identified in §1905(a) of the Act, some HHAs choose to offer additional services which are clearly non-medical in nature. Such services are typically comprised of housekeeping, chore, or companion services. The HHA makes these services available to individuals who choose to pay for them privately, and/or individuals who are provided these services from other programs, such as a State Medicaid Home and Community-Based Services (HCBS) Waiver Program under §1915(c) of the Social Security Act. The HHA may offer these services to current patients of the HHA (to supplement the skilled services available), to previous patients who have been discharged from skilled care, and to other individuals in the community who request them.

Many individuals who receive these non-medical services are frail, elderly or disabled and request these services because they are unable to perform them independently and need this kind of assistance to remain in the home environment.

In addition to promoting the health and safety of individuals, §1891(b) of the Social Security Act also directs the Secretary to ensure that requirements "promote the effective and efficient use of public moneys." This statutory direction is especially pertinent in the question of whether expenses ought always to be incurred for a comprehensive assessment and care plan when the only service requested from an HHA by an individual is a chore or other clearly non-medical service. When this is the case, we will not consider the individual to be a patient of the HHA in the traditional sense of the term, and requirements that must apply to patients will not be required in such limited situations (e.g., the requirement for a comprehensive assessment under 42 CFR 484.55 will not apply).

The Medicare HHA CoPs do not apply to those individuals who receive only chore services or other clearly non-medical services from the HHA. Non-medical services include chore services, companion services, household maintenance and repair services, lawn and tree services, and clearing walkways. To the extent that there is ambiguity as to whether a service is non-medical or medical, we will incline towards the medical interpretation and consider the CoPs to apply.

CMS considers as a medical service any hands-on service, personal care service, cueing, or activity that is in any way involved in monitoring the patient's health condition. As soon as the HHA provides any Medicare service to an individual, or any standard service permitted by Federal law under the Medicaid State Plan (such as personal care), we will consider the individual to be receiving medical care. The CoPs will apply for all services rendered to such an individual. For example, the CoPs would apply in the case of an individual who received both chore services and personal care (regardless of funding

source), but would not apply in the case of an individual receiving only chore services from the HHA.

HHAs are required as a part of the patient rights CoP to advise the patient of the extent to which payment for HHA services may be expected from Medicare or other sources and the extent to which payment may be required from the patient. The HHA should explain to a beneficiary who is ending a Medicare episode and continuing to receive chore services that Medicare does not pay for those services.

HHAs may develop their own comprehensive assessment for each required time point under the regulations at 42 CFR 484.55 for those patients receiving personal care services only regardless of payor source. The assessment may be performed any time up to and including the 60th day from the most recently completed assessment.

The HHA must continue to meet all State licensure and State practice regulations governing the provision of service to this population. Where state law is more restrictive than Medicare, (e.g., State law or State Medicaid HCBS requires the HHA to comply with CoPs when providing only chore services) the provider needs to apply the State law standard as well.

Note that this instruction does not supersede any current policy related to Medicare coverage and eligibility rules or instructions from the Regional Home Health Intermediaries. The HHAs that provide non-medical services must also ensure that fiscal accounts are structured and maintained in conformance with CMS regulations and generally accepted accounting standards.

2182 - Organization of HHA
(Rev. 1, 05-21-04)

Parent HHA

The parent HHA is that part of the HHA that develops and maintains administrative control of subunits and/or branch offices. Services are provided by the parent HHA.

Branch Offices

A branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the CoPs as an HHA. When the surveyor is conducting a survey of an HHA with branch offices, ascertain from HHA records whether the branch offices are provided adequate supervision by the parent agency and whether they are, in fact, sufficiently close to the parent agency to be considered branch offices rather than subunits. If this judgment cannot be made without direct observation, the surveyor should visit the branch office to make this determination.

When reviewing records and conducting visits to patients' homes, the surveyor selects some records and/or schedules some home visits to patients who are served by each branch office. The surveyor may also conduct a standard survey of the HHA at a branch office. When conducting a survey at a branch, the surveyor may request that all necessary documentation for review be transported to the branch. This may include, but not be limited to, a sample of clinical records from the parent and any other branches, governing body minutes, personnel records, etc.

Subunits

A subunit is a semi-autonomous organization that:

1. Serves patients in a geographic area different from that of the parent agency; and

2. Must independently meet the HHA CoPs because it is too far to share administration, supervision, and services on a daily basis.

The standards on governing body, administrator, and under the circumstances noted here, the group of professional personnel, will be found met by subunits if they are met by the parent agency. The parent agency's group of professional personnel may serve as the subunit's group of professional personnel if that group is effectively pursuing its responsibilities for the HHA and its subunits. The parent agency's and subunit's records, i.e., policy statements and minutes of group meetings, must establish that attention is being paid to the subunit's operation in delivering services. The subunit may establish its own group, or the parent HHA may have a subcommittee of its group deal specifically with the subunit's policies and procedures.

The SA completes an HHA Survey and Deficiencies Report (Form CMS-1572 (a), (b), and (e)), Form CMS-2567, and all other applicable documents for the parent organization and each subunit. The SA does not conduct the initial survey of a subunit prior to the initial survey of the parent agency.

Subdivisions

A subdivision is a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the CoPs for HHAs. A subdivision may have subunits and/or branch offices and, if so, is regarded as a parent agency.

2182.1 - Characteristics Differentiating Branches From Subunits of HHAs

(Rev. 1, 05-21-04)

The comparisons on the following pages identify and clarify policies that assist in making a distinction between a branch and a subunit. The surveyor discusses any discrepancies with the administrator or his/her designee and notifies the CMS RO.

Administrative Functions (Relationship with Parent Agency)

Branch - Not autonomous. Is part of the HHA and shares administration, supervision and services with the parent agency on a daily basis. The administration at the parent agency is aware of the staffing, patient census and any issues/matters affecting the operation of any given branch. The branch location provides services within a portion of the total geographic area served by the parent agency.

Subunit - Semi-autonomous. Is located at such a distance from the parent agency that it is incapable of sharing administration, supervision, and services on a daily basis. Serves patients in a geographic area different from that of the parent. A subunit may have a branch.

Compliance with CoPs

Branch - Does not have to independently meet the CoPs as an HHA.

Subunit - Independently meets all CoPs as an HHA.

Organizational Structure (See 42 CFR Part 484.14.)

Branch - The lines of authority and professional and administrative control are clearly delineated in both organizational structure and in practice and can be traced to the parent agency.

Subunit - The lines of authority and professional and administrative control are clearly delineated in both organizational structure and in practice.

Supervision (See 42 CFR Part 484.2.)

Branch - Supervision is shared between the parent agency and the branch. However, if the branch is so large (i.e., has a large staff and serves many patients) or is so distant that it is impossible for a supervisor of a specific discipline to accomplish adequate supervision, the branch should be requested to convert to a subunit.

Subunit - The subunit functions independently of the parent, and consequently, supervision is provided by staff designated by the subunit.

Administrator (See 42 CFR Part 484.4.)

Branch - The administrator of the HHA maintains an ongoing liaison with the branch staff and the group of professional personnel. In order to accomplish this activity, sufficient time must be allocated for sharing information with all the

parties mentioned. The branch is located sufficiently close to the parent to share administration. The administrator is apprised of, and resolves issues affecting patients in branch(es) as well as the service area(s) covered by the parent.

Subunit - Is semi-autonomous and maintains its own administrative staff. Functions as an independent entity.

Supervising Physician or RN (See 42 CFR Part 484.14(d).)

Branch - The location of the branch, in relation to the parent, is such that the parent is able to assure adequate supervision during all operating hours.

Subunit - Supervisory M.D. or RN is available during all operating hours.

Personnel Policies (See 42 CFR Part 484.14(e).)

Branch - The parent office maintains current personnel records on all staff. A statement of personnel policies is maintained in each branch for staff usage.

Subunit - Personnel policies and records must be maintained at the subunit.

Coordination of Patient Services (See 42 CFR Part 484.14(g).)

Branch - Information concerning care provided to patients is communicated to staff in branches and parent agency, particularly when staff of one organizational unit (i.e., branch) does not base its practice at that site. (Example: A PT provides services to patients managed by the parent agency as well as patients managed by the branch. Most of the PT's time is spent with patients from the branch, although occasionally a patient followed by the parent agency is included in his/her workload. The PT is expected to coordinate care with staff in each organizational unit (i.e., branch or parent) as required by the patient's needs and as practice dictates.

Subunit - Since the subunit is a semi-autonomous entity, coordination is simplified because staff is generally available on a regular basis or can easily be reached to discuss and implement the coordination of patient care.

Services Under Arrangements (See 42 CFR Part 484.14(h).)

Branch - Contracted arrangements with various entities are the responsibility of the parent agency, even when the contracted services are used exclusively by the branch.

Subunit - Maintains contracts with various entities to provide services. The subunit is responsible for the administration and supervision of those services. Parent agency monitors subunit services provided under arrangements.

Group of Professional Personnel (See 42 CFR Part 484.16.)

Branch - The annual review of the agency's policies is conducted by a group of professional personnel. Their focus is directed on service delivery throughout the entire agency including the parent agency and branch(es).

Subunit - The parent agency's group of professional personnel may also serve as the subunit's group of professional personnel. The parent agency and subunit's policy statements and minutes of group meetings must include specific references to issues addressed in the delivery of home health services. The subunit may establish its own group of professional personnel or it may form a subcommittee of the parent HHA's group which deals specifically with the subunit's policies and procedures.

Clinical Records (See 42 CFR Part 484.48.)

Branch - Should retain the clinical records for its patients, since the branch site is where the professionals providing the services are located. Duplicate records need not be maintained at the parent agency, but must be made available to the surveyor upon request.

Subunit - Maintains clinical records on all its patients.

2182.2 - Guidelines for Determining Parent, Branch, or Subunit
(Rev. 1, 05-21-04)

The following guidelines should be used when making a determination as to whether a proposed HHA unit is a parent, branch, or subunit as defined at 42 CFR Part 484.2:

A. Supervision

Supervision of the branch staff is critical to the provision of quality care for patients. The regulations require the branch to be within the parent's geographical service area and close enough to the parent to share supervision, administration, and services on a daily basis. Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Supervision at the branch must be adequate to support the care needs of the patients.

Supervision of services requires that a qualified person be physically present to directly supervise the provision of services by any individual who does not meet the qualifications specified at 42 CFR Part 484.4. For individuals that do meet the qualifications specified at 42 CFR Part 484.4, the supervisor does not have to be physically present during the provision of all services. The use of telephones, pagers, facsimile machines, or other electronic devices does not eliminate the requirement for the physical presence of the supervisor. The parent may appoint an effective full time branch

supervisor or manager as long as this individual is and remains under the supervision of the parent.

B. Distance

Mileage and travel times from the parent to the branch are significant factors to consider because they are implicitly referenced in the regulations. However, each alone would not be the single issue in determining appropriateness. The regulations require that a branch be "sufficiently close" to share administration, supervision, and services in a manner that makes it unnecessary for the branch to meet the CoPs on its own. To accomplish this, the parent agency must be physically located so that sharing of administration, supervision, and services with the branch can occur on a daily basis. If the parent is not capable of sharing such functions with the branch on a daily basis, then the non-parent office or location must independently meet the CoPs.

C. Geographic Area

"Geographic area" generally means the location, i.e., address of the clients served by the parent and non-parent. If the non-parent office is located within a portion of the total geographic area served by the parent, but serves patients outside the geographic area, then the non-parent should not be a branch and would be classified as a subunit. (If the State does not recognize subunits, the HHA would seek a new provider number and establish a parent location.) This is consistent with the subunit definition that applies to a non-parent office that serves patients in a geographic location different from the parent.

D. Sharing Administration, Supervision, and Services

In addition, consider that the sharing of HHA administration, supervision, and services may occur at any time and could flow in either direction, i.e., parent to branch or branch to parent.

If an entity within the HHA's organizational structure reports directly to the home or corporate office or some other office other than the alleged parent HHA, it is more likely a subunit rather than a branch. As a subunit it would need to independently meet the CoPs.

If the parent HHA and the non-parent use totally different staffs, it is less likely they are sharing functions on a daily basis, and it is therefore less likely that a parent/branch relationship exists.

The fact that the non-parent office is located in a different metropolitan statistical area (MSA) from that of the parent is a consideration in making determinations about geographic areas. Commuting patterns are one consideration in the establishment of MSAs. If the parent and non-parent are in different MSAs, it may reflect that the non-parent is not within sufficient proximity to the parent to share functions on a daily basis. This is especially true if the parent and non-parent are in non-contiguous MSAs.

If the parent and non-parent are incapable of sharing emergency functions, including services, on a daily basis, the non-parent is probably not a branch.

State licensure laws that define parent, branch, and/or subunit are a consideration in making non-parent determinations, but it is the definitions in the Federal regulations (42 CFR Part 484.2) that must be satisfied in making parent, branch, or subunit determinations. If an HHA operates across State lines, follow the instructions in §2184 of the State Operations Manual. The SA in the State in which the parent is located should take the lead in coordinating with the adjacent State to resolve parent and non-parent issues.

The fact that the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program has awarded branch status to a location will not affect CMS' parent/non-parent decision. CMS' determination will be based on its independent application of its regulations to the facts in the case.

2182.3 - Processing Change From Branch to Subunit
(Rev. 1, 05-21-04)

In most cases, a survey of an existing, previously approved branch that you now determine should be a subunit will not be needed. In such a situation, follow the existing survey and certification rules for issuing a provider agreement and number to the subunit, and use an effective date agreed upon by the CMS RO. However, if you discover a "branch" that has never been identified to the SA or CMS that is subsequently determined to be a subunit, an onsite survey in accordance with the usual survey and certification rules will apply. Note that a subunit may have branches. An onsite survey will also be necessary for any location where the HHA has not provided services to Medicare beneficiaries in the past that the HHA now proposes to operate as a branch, and that CMS determines on the basis of the information provided, is a subunit.

2182.4 - CMS Approval Necessary for Non-Parent Locations
(Rev. 1, 05-21-04)

As part of the provider certification process, an existing Medicare-approved HHA must provide notification to CMS through the SA of its proposal to add a non-parent location, i.e., branch or subunit.

2182.4A - Notification by HHA to Add Non-Parent Location
(Rev. 1, 05-21-04)

- The notification should include the following information:
- Address and phone number of the branch/subunit;
- Organizational lines under the parent;

- How supervision will occur;
- Services provided directly and under arrangement; and
- Geographic area (counties, cities, zip codes).

The parent HHA should:

- Identify all branch staff and their job descriptions;
- Provide proof of staff qualifications (resume, licensure, aide training, etc.);
- Provide contracts for any services provided under arrangement;
- List any services shared with the HHA parent;
- Define service area and any intention to cross State lines (need a reciprocal agreement between States and RO approval at that time);
- Provide policy for addressing clinical and other emergency situations;
- Provide plans for addressing staff absenteeism;
- Identify any high-tech services provided;
- Identify how staff will coordinate care and services;
- Identify the person who will resolve patient care issues at the branch, and explain how supervision by the HHA parent will occur;
- Attach organizational chart delineating lines of authority, professional and administrative control for the HHA and the branch; and
- Provide certificate of need, if applicable.

2182.4B - SA Considerations in Reviewing a Request for Branch Determination

(Rev. 1, 05-21-04)

The SA should review the HHA's proposal for:

1. HHA's ability to supervise the branch to assure the provision of quality care for the patients served by the branch. The following information should be considered:

- The HHA's supervising nurse or physician, as required by 42 CFR 484.14(d) must be available by phone or other means of communication during operating hours. The presence of an effective branch supervisor or manager, who is formally appointed by and under the direct supervision of the HHA parent, is permissible;

- The HHA's governing body is responsible for the overall operations of the parent and branch;

- The HHA parent may use technological means for supervision in conjunction with periodic onsite visits. The HHA parent should be aware of the staffing, patient census and any issues/matters affecting the operation of the branch. The lines of authority and professional and administrative control should be clearly delineated in the HHA's organizational structure and in practice and should be traced to the HHA parent agency;

- The administrator of the HHA must be able to maintain an ongoing liaison with the branch to ensure that staff is competent and able to provide appropriate, adequate, effective and efficient patient care so as to ensure that any clinical and/or other emergencies are immediately addressed and resolved;

- The HHA must be able to maintain a system of communication and integration of services throughout the agency, whether provided directly or under arrangement, that ensures the identification of patient needs, an ongoing liaison between all disciplines providing care, and physician availability when necessary for relevant medical issues;

- The HHA parent should have a system in place to review patient records and care at the branch to ensure that the branch is implementing all policies and procedures and complying with the CoPs for all patients;

- The HHA parent must be able to monitor branch activities (clinical and administrative) and the management of services, as well as personnel and administrative issues;

- Depending on the organization, the HHA's administrator, quality improvement personnel, supervisory personnel etc., should conduct periodic onsite visits to the branch to ensure the delivery of quality care;

- The HHA parent provides ongoing in-service training to ensure that all staff is competent to provide care and services;

- The HHA parent is responsible for any contracted arrangements with any individuals or organizations, even when the contracted services are used exclusively by the branch; and

- Whether the required group of professional personnel, which reviews the agency's policies, is directed to service delivery throughout the entire agency, including the HHA parent and any branches.

2. The HHA's past compliance history;

3. Relevant State issues and recommendations including a required written reciprocal agreement between the States to assure that at least one of the SAs assumes responsibility for any necessary surveys of the branch in situations in which an HHA provides services across State lines; and

4. A review of the ability of the branch office to meet the regulatory definition of a branch as defined in 42 CFR 484. The regulations require the branch to be within the HHA's geographical service area and close enough to the HHA to share supervision, administration and services on a daily basis. While mileage and travel times are significant factors to consider because they are implicitly referenced in the regulations, each alone should not be the single issue in determining approval or denial of the branch. The following information should be considered:

    - Services offered by the HHA parent are also offered by the branch;

    - The branch and its service area must be located within the HHA parent's geographic service area. If the branch is extending the current geographic service area, the new geographic area must be contiguous.

While all of the above factors should be considered when reviewing branch office applications, the focus should be on the ability of the HHA to demonstrate how it can monitor all services provided in its entire service area, including any branch offices, to ensure compliance with the conditions of participation found at 42 CFR 484. The decision to approve a branch should be based on the HHA's ability to adequately supervise the branch to assure that the quality and scope of items and services provided to all patients is of the highest practicable functional capacity for each patient so as to meet their medical, nursing, and rehabilitative needs. If a review of an HHA's branch office application is determined to be insufficient, the disapproval letter should include some discussion of these criteria.

2182.4C - Onsite Monitoring by the SA
(Rev. 1, 05-21-04)

Onsite monitoring of the operations of an approved branch should reveal that:

- A copy of the HHA's policies and procedures is maintained in each branch. Branch office personnel should be knowledgeable of the policies and consistently apply them;

- Methods of communication between HHA parent and branch assure that all patients receive the necessary care and services identified through the comprehensive assessment and plan of care;

- The branch retains the active clinical records for its patients. Duplicate clinical records need not be maintained at the HHA parent, but must be available to the surveyor upon request; and

- Patients are receiving appropriate care and services at the branch.

CMS must then determine if the CoPs continue to be met with the inclusion of the additional location. In the absence of notification, CMS cannot determine whether the requirements critical to health and safety are met at the non-parent location. A provider may not bill Medicare for services provided by either a branch or subunit where the branch or subunit is not a part of an approved HHA or where the branch or subunit has not been determined to meet the applicable CoPs.

While the HHA may notify the SA of its proposal to establish a non-parent location, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO which has the authority for determining the non-parent's status as a branch or subunit.

The CMS RO will review each HHA's request for a branch office on a case-by-case basis, and consider all the national guidelines. The CMS RO will communicate its final decision in writing to the parent and copy the SA and the regional home health intermediary (RHHI). The approval letter should include notification of the branch approval and the assigned Federal branch ID number. The RO should enter the branch ID number into ASPEN prior to sending the letter to the HHA, so that the branch can begin providing services and collect and submit OASIS data on receipt of the approval letter. Any decision to deny the request for a branch office should include the full range of the reasons supporting the denial. Use the Model Denial Letter, Exhibit 284, as appropriate and copy the SA.

2182.4D - Drop Sites

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

An HHA may choose to operate a drop site if permitted to do so by State and local law and if the location does not meet the Medicare definition of a branch. HHAs that allow these locations to cross the line from drop site to branch are out of compliance with the Medicare requirements. The HHA should not assign staff to these locations, accept referrals at these locations, advertise them as a part of the HHA, or operate them in any other way as branches of the HHA. HHAs that are unsure if the location meets the definition of a branch may seek advice from the State Survey Agency. If the location does meet the definition of a branch, it must request CMS approval before providing services from this location. The HHA's policies on drop sites should reflect current Federal and State requirements, including compliance with the Health Insurance

Portability and Accountability Act of 1996 privacy requirements. While these sites would not be subject to routine surveys, they may be subject to state or RO inspection at any time. Any violation would be addressed by the State Survey Agency and referred to the CMS RO for any necessary program integrity investigation and follow up.

2182.5 - Branch Identification Numbers

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

An identification number is assigned to every branch of a parent HHA and subunit, as applicable, effective January 1, 2004. The identification system uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent or subunit to the branch. Having a system to identify branches gives CMS the capability of associating survey results with individual HHA branches. Also, submission of branch identification numbers on Outcome and Assessment Information Set (OASIS) assessments will provide the capability of developing outcome reports that will help HHAs differentiate and monitor the quality of care delivered by their agencies down to the branch level.

Each branch is numbered with the same Federally assigned provider number as the parent or subunit with two modifications. There is a "Q" between the state code and four-digit provider designation plus three more digits for a 10-character branch identifier. Branch identification numbers are to be used only once. In the event that an HHA branch closes, its unique branch identification number is terminated and not re-used to identify another branch of that HHA or subunit.

EXAMPLE:

- ABC Home Health Agency in Alabama has three branches.
- ABC Home Health Agency in Alabama = Medicare Provider number 017001.
- ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.
- As directed by the ROs, HHA branch identification numbers will be entered into the Automated Survey Processing Environment (ASPEN) system along with the branch demographic information.

Assignment of Branch Identification Numbers

The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. As surveys are conducted, SAs should verify that the information they have on branch locations is current and accurate. As branch identification numbers are assigned, HHAs and their

respective branches are informed of their assigned branch identification number(s). A sample letter is attached available at (Exhibit 151) for use by the RO or SA to notify HHAs of their branch identification number(s). HHAs will need this information to enter on OASIS item M0016 (Branch ID). HHAs and subunits that do not have branches will not be assigned any branch IDs.

Form CMS 1572 and Assignment of Branch Identification Numbers

ROs are responsible for assigning branch identification numbers according to the RO's existing policies for assignment of provider numbers. The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. Current branch information is collected on every state agency home health survey.

When future HHA branches are approved, the ROs must assure that all branch locations nationwide are identified, enumerated, and entered into ASPEN prior to sending the approval letter to the HHA. As surveys are conducted, states should verify that the information they have on branch locations is current and accurate.

Branch Identification Numbers and OASIS

As branch identification numbers are assigned, the RO must ensure that HHAs and their respective branches are informed of their assigned branch identification number. At this time the fiscal intermediaries are not in need of branch identification information**.**

HHAs will need this information to complete OASIS item M0016 Branch ID. Detailed instructions for completion of M0016 by parent HHAs, subunits, branches, and HHAs and subunits without branches are included in M0016 Branch ID in Chapter 8 of the OASIS Implementation Manual.

2183 - Separate Entities
(Rev. 1, 05-21-04)

The surveyor must be able to identify the boundaries of the entity seeking certification or recertification. The Medicare CoPs, in accordance with §1861(o)(6) of the Act, are applicable to all individuals served by the HHA and not just Medicare beneficiaries. While the purpose of the CoPs is to help ensure proper care for Medicare beneficiaries, the CoPs do this by defining the standards for an HHA in which Medicare beneficiaries may be treated, instead of establishing requirements applicable only to Medicare beneficiaries served by the HHA.

Neither the Act nor the Medicare regulations define a "separate entity" with respect to HHAs that Medicare approves as an HHA in accordance with the Act and the CoPs. When an HHA alleges that it is operating a separate entity to which the CoPs do not

apply, ask the HHA or its parent organization for information that will allow you to differentiate between it and the HHA. The HHA may be identified as a department, program, or component of the larger organization. Use the following guidelines, on a case-by-case basis, to assist you in determining if a separate entity exists. The following criteria should be **considered** in making a decision regarding a separate entity:

- Operation of the HHA;
- Consumer awareness; and
- Staff awareness.

2183.1 - Operation of the HHA
(Rev. 1, 05-21-04)

Ask the HHA administrator to describe the organizational, functional, and clinical boundaries of the Medicare-certified program in relation to any other programs the larger organization offers. Other programs should be separate and distinct from the HHA. Ensure that the HHA has:

- Separate policies and procedures for admission to the HHA, including separate consent forms;
- Separate clinical records for all patients receiving HHA services;
- Current licensure, in accordance with State requirements. In States which license HHAs, review if the State has licensed separately the approved HHA and the separate entity, or has licensed the separate entity as another type of provider or supplier;
- Current listing of staff employed by or contracted to the HHA;
- Personnel records;
- Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- Separate budgets.

2183.2 - Consumer Awareness
(Rev. 1, 05-21-04)

The organization should differentiate the services of the HHA from other services offered by the larger organization. Ask the HHA for a copy of any brochure the HHA uses to describe itself to the community. Any applicable brochures should identify the HHA services as separate and distinct from other programs, departments, or entities operated

by the HHA. The HHA should be differentiated from other programs, departments or entities of the organization in listings, advertisements, etc. Written material should clearly identify the HHA as separate and distinct from other programs, departments or entities of the organization.

2183.3 - Staff Awareness
(Rev. 1, 05-21-04)

The HHA staff should be knowledgeable about the HHA's policies and procedures, the regulatory requirements related to their role in the delivery of care in an HHA, and be able to identify the difference in services they provide for the HHA and other programs, departments, or entities of the organization.

Personnel who divide time between the separate entity and the HHA must be appropriately trained to deliver HHA services.

If the State survey agency determines, based on the information provided by the HHA or for other reasons, that the HHA does not have a separate entity, or if the HHA or parent organization is unable or unwilling to provide the information, inform the HHA that:

- It is in violation of the provisions of §§1861(o) and 1891 of the Act which require compliance with the CoPs, particularly those conditions that relate to clinical records and disclosure of the ownership of the HHA;

- It is in violation of its agreement with the Secretary under §1866 of the Act and the regulations related to this agreement (42 CFR Part 489.53(a)) because it has failed to provide information about ownership and information concerning clinical records;

- It is in violation of §1128(b)(12)(A) of the Act because it has denied access to records to determine compliance with the CoPs, including those that relate to the OASIS requirements; and

- It may be in violation of various requirements related to its Medicare cost reports, which mandate information about all of the HHA's clients in order to properly pay Medicare costs, and that the HHA's intermediary must be notified about the allegation of separate entities. (See 42 CFR Parts 413.5(b)(3), 413.9, 413.13(f)(2)(ii), 413.17, 413.50(b), 413.53(a), and 413.80(d).)

The SA should report these separate entity situations to the CMS RO, along with any recommendations the State has concerning the operation of two distinct entities. The State should also indicate whether the HHA refused access to records or information that make it impossible for the surveyor to make a determination concerning whether the applicant or approved HHA complies with the HHA CoPs.

The surveyor should inform the approved HHA that the SA must report the alleged separate entity to the CMS RO that in turn must report this information to the intermediary and, if necessary, to the State Medicaid Director.

2184 - Operation of HHAs Cross State Lines

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

When an HHA provides services across State lines, whether through its own personnel, or a branch, or subunit, each respective SA must be aware of and approve the action. Each SA must verify that applicable State licensure, personnel licensure, and other State requirements are met in its respective State. Any branch or subunit of the HHA must meet applicable State and local laws in the State that it is serving.

In most circumstances, the provision of services across State lines is appropriate. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of HHA services.

When an HHA provides services across State lines, it must be certified in all States in which it provides services and its personnel must be qualified in all States in which they provide services. Certification activities within a particular State are done by the appropriate SA for that State. The involved States must have a written reciprocal agreement permitting the HHA to provide services in this manner. The reciprocal agreement must indicate that both States are aware of their respective responsibilities for assessing the HHA's compliance with the CoPs within their State. The agreement should assure that home visits are conducted to a sample of all patients served by the HHA in all States served by the HHA.

The CMS RO will review the required reciprocal agreement between the States to assure that the SA in which the branch resides is assuming responsibility for any necessary surveys of the branch. If the SAs involved are unable to come to a reciprocal agreement on assuring the necessary surveys of the branch, the branch should not be approved. The provision of interstate service without a written reciprocal agreement could severely undermine a State's ability to fulfill its statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements. It is at the discretion of the States to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit 152 contains a model reciprocal agreement document that States may use to assist them in fulfilling their statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements when an HHA provides services across State lines. In those States that have a reciprocal agreement, providers are not required to be separately approved in each State; consequently they would not have to obtain a separate Medicare provider agreement/number in each state. Providers residing in a State that does not have a written reciprocal survey agreement with a contiguous State are precluded from providing services across State lines.

If a State does not have a written reciprocal agreement with other States, the HHA must establish a separate parent agency or subunit in the State in which it wishes to provide services.

In the event that an HHA operates in two CMS ROs, the CMS RO responsible for the State in which the parent resides should take the lead in assuring that the required survey and certification activities are met.

A branch office may also be physically located in a neighboring State if it is near enough to the parent agency to share administration, supervision, and services on a daily basis, and if the SAs responsible for certification in each State approve the operation.

Subunits of an HHA may be physically located in more than one State. A separate certification is made by the SA where each subunit is located.

While the HHA may notify the SA of its proposal to provide services on an interstate basis, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO that has the Medicare approval authority of the parent HHA and assumes final responsibility for approval of the operation across State lines.

2186 - Health Facility-Based HHAs

(Rev. 1, 05-21-04)

An HHA based to a hospital, SNF, hospice, or rehabilitation facility is expected to be an integral but subordinate part of the institution. Administrative and fiscal controls may be exercised over the HHA. However, the HHA's policies, personnel files, and clinical records must be separate and identifiable. Time records must be maintained for all personnel who provide home health services and must be identifiable as home health regardless of whether they are part-time or full-time. The HHA's concurrent use of personnel employed by a hospital, SNF, hospice, or rehabilitation facility is acceptable provided the HHA's operating hours are definite and not arbitrarily subject to the operation of the other institution, and provided the other institution's operation does not interfere with the HHA's maintaining compliance with the CoPs.

An HHA's services must be supervised by an employee of the HHA. If members of the institution's governing body serve the HHA as the group of professional personnel, minutes must reflect meetings of this group. Clinical records may be maintained in the record room or department. However, the clinical records must contain information pertinent only to the delivery of home health services, and should be readily available for either claims review or review by the SA.

In surveying the health facility-based HHA, the SA considers the institution's ability to share its administrative structure and personnel in fulfilling the needs and requirements of the HHA on a continuing basis. The CoPs for HHAs must be applied and met independently.

2188 - Survey of State-Operated HHAs
(Rev. 1, 05-21-04)

The same general procedures applicable to surveying other types of HHAs apply to HHAs operated by a State. However, individuals associated with the HHA in an administrative, supervisory, or service capacity must not be involved in the certification and consultation functions of the SA.

2194 - Surveying Health Maintenance Organization (HMO)-Operated Home Health Agencies (HHAs) Providing Home Health Services Through Medicare Survey and Certification Process
(Rev. 1, 05-21-04)

The HMOs (Medicare+Choice) which contract with Medicare to furnish HHA services may provide such services either directly by the HMO or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 417.416(a) and
42 CFR Part 422.20(b)(3).)

If an HMO provides home health services directly as an integral part of the HMO, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare provider number, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, that an HHA approved under 42 CFR Part 484.1 would have to comply with.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, and documents its findings on Form CMS-1572. The SA completes Form CMS-2567, obtains a PoC when necessary, and sends this information along with a completed Form CMS-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2195 - Guidelines for Determining Survey Frequency
(Rev. 1, 05-21-04)

Section 1891(c)(2)(A) of the Act states that standard surveys will occur not later than 36 months after the previous standard survey, and that the Secretary shall establish a frequency for surveys within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

A. An HHA may be placed on a 36-month survey cycle if it meets the following criteria:

- No condition-level deficiencies in the last three recertification surveys;
- No deficiencies at 42 CFR Part 484.18 or 42 CFR Part 484.55 in the previous standard survey; and
- No complaints resulting in deficiency citations since the previous survey.

In order to avoid giving notice of the survey, conduct the standard survey during a range of 30 - 36 months.

B. An HHA may be placed on a 12 - 36-month survey cycle if the following criteria are met:

- No condition-level deficiencies within 24 months of the most recent survey;
- No complaints resulting in deficiency citations since the previous survey; and
- Deficiencies at 42 CFR Part 484.18 and/or 42 CFR Part 484.55 in the previous standard survey, and the plan of correction was acceptable. In these situations, consider the following criteria in determining survey frequency:
    - Number of standard-level deficiencies cited;
    - Deficiencies cited under 42 CFR Parts 484.10 and/or 484.14(g); 484.18, and/or 484.55;
    - Number and resolution of complaints received concerning the HHA;
    - Changes in HHA management; and
    - Licensure information.

We expect that the majority of these HHAs will be surveyed at least every 24 months; however, SAs may use their discretion in surveying more or less often.

C. An HHA must be placed on a 12-month survey cycle if the following criteria are met:

- An HHA has been Medicare-approved for less than 3 years at its most recent survey;
- An HHA has had a change of ownership since the previous standard survey;

- An HHA had a condition-level deficiency cited within 24 months;
- An HHA had a complaint survey resulting in deficiency citations since the last standard survey; or
- An HHA has been reviewed by a State, regional, or national fraud and abuse initiative.

In order to avoid giving notice of the survey, you should conduct the standard survey during a range of 9 - 15 months.

D. More Frequent Surveys

An HHA that fails to meet one or all of the Medicare CoPs will be considered to be providing substandard care and will require closer scrutiny. Such an HHA will be placed under the appropriate termination procedures until the HHA comes into compliance with the CoPs or is terminated. If the HHA comes back into compliance with the CoPs, the HHA will receive a standard survey within 4 - 6 months from the date that compliance was established. If the HHA continues to comply with the CoPs, then the HHA will be placed on the 12-month survey cycle until the HHA is free of condition-level deficiencies for no less than 2 consecutive years.

E. Random Surveys

Each SA will randomly select, on an annual basis, a 5 percent sample of HHAs on the 36-month survey cycle. Surveyors will conduct a standard survey on this sample of HHAs within 16 - 20 months following the recertification survey. Appropriate survey frequency decisions may be made based on the results of the random survey.

SURVEY FREQUENCY GUIDELINES	
Frequency	**Requirements**
36 months	No CoP(s) out in the last 3 recertification surveys; AND
	No deficiencies at 42 CFR Part 484.18 (i.e., acceptance of patients, PoC, and medical supervision) or 42 CFR Part 484.55 Comprehensive Assessment of Patients in the previous standard survey; AND
	No complaints with deficiency citations since the previous survey.
12 - 36 months	No CoP(s) out within 24 months of the most recent survey; AND
	No complaints with deficiency citations since the previous survey; AND
	Deficiencies at 42 CFR Part 484.18 and/or 42 CFR Part 484.55 in the previous standard survey with an acceptable plan of correction. In these situations, the State also considers the following criteria in determining survey frequency:
	Number of standard-level deficiencies;
	Deficiencies cited under 42 CFR Part 484.10 (i.e., patient rights), Part 484.14(g) (i.e., coordination of patient services), Parts 484.18, and 484.55;
	Number and resolution of complaints received concerning an individual HHA;
	Changes in HHA management; and
	Licensure information.
12 months	Medicare-approved for less than 3 years at its most recent survey; OR
	Change in ownership since the previous standard survey; OR
	CoP(s) cited within 24 months of the most recent survey; OR
	Complaint survey with deficiency citation since the last standard survey; OR
	Review by a State, regional, or national fraud and abuse initiative.
4 - 6 months	CoP(s) out and resolved.

2195.1 - Tracking and Monitoring the Survey Cycles

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

The following codes should be entered into the ASPEN system to enable the SAs and ROs to track and monitor the survey cycles of HHAs except that the coding is optional for 2006 as CMS tests an alternate system. States may, however, elect to continue the coding. If so, the code should be entered when the survey is completed and the survey results are ready for upload to the national system. Surveyors or other appropriate staff should clearly mark the length of the survey cycle on the Application (Form CMS-1572A) tab in the designated field. The codes are outlined below:

A = 36 months;
B = 12-36 months;
C = 12 months;
D = 4-6 months; and
E = 18 months (5% sample).

For 2006, a CMS-generated list will be used to target those HHAs that will be surveyed more frequently than once every 3 years. For all other years, the following will apply:

With the exception of code B, the codes will identify the survey interval for all HHAs, i.e., code A HHAs will be surveyed every 36 months, code C HHAs will be surveyed every 12 months, etc. Survey the majority of code B HHAs at least every 24 months; however, SAs may use their discretion in surveying more or less frequently. HHAs that meet the criteria for a code A as the result of their last survey may be selected for the 5% sample in 18 months and entered into the system as a code "E."

Once the survey frequency code has been entered and uploaded to the national system, the SA shall have the responsibility to enter any subsequent changes to the survey frequency code, providing the reason for the change. A history of survey frequency code changes, the reasons for each change, and other information as required by CMS will be maintained on the national system. The two most likely reasons to change the survey frequency code between surveys are a complaint investigation with deficiency citations or a change of ownership. The SA and RO should keep apprised of such events by generating reports that track HHA survey frequency code change details.

2196 - HHA Survey Process for Determining Quality of Care
(Rev. 1, 05-21-04)

The HHA survey process provides for a standard survey, a partial extended survey, and an extended survey. All HHAs must undergo a standard survey. The standard survey determines the quality and scope of patient care services provided by an HHA as measured by indicators of medical, nursing, and rehabilitative care. Each HHA that is found to have one or more condition-level deficiencies under a standard or partial extended survey must undergo an extended survey to review and identify the policies and procedures which produced the substandard care and to determine if the HHA meets all of the CoPs.

An HHA may also be subject to a partial extended or extended survey at the discretion of CMS or the State.

Any data tag that is not a condition-level data tag is a standard-level tag. Any deficiency at any data tag that is not a condition-level deficiency is a standard-level deficiency.

2196.1 - Definitions
(Rev. 1, 05-21-04)

2196.1A - Standard Survey
(Rev. 1, 05-21-04)

Conducted to determine the quality of care and services furnished by the HHA as measured by indicators of medical, nursing, and rehabilitative care. The surveyor uses the Functional Assessment Instrument (FAI) (Form CMS-1515) to record information obtained during home visits and clinical record reviews. The surveyor reviews the HHA's compliance with:

- Patient rights (42 CFR Part 484.10);
- Release of Patient Identifiable OASIS Information (42 CFR Part 484.11);
- Federal, State, and local laws and regulations, the disclosure of ownership and management information, and accepted professional standards and principles (42 CFR Part 484.12);
- Coordination of patient services (42 CFR Part 484.14(g));
- Acceptance of patients, PoC, and medical supervision (42 CFR Part 484.18);
- Home health aide services (42 CFR Part 484.36);
- Clinical records (42 CFR Part 484.48); and
- Comprehensive assessment of patients (42 CFR Part 484.55).

Section 1891(c)(2)(C)(i)(II) of the Act requires that the standard survey include "a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care." Therefore, it is essential that the surveyor review the HHA's compliance with the comprehensive assessment regulation (42 CFR 484.55) (which incorporates the OASIS data elements) as well as identifies how the HHA defines, plans for, delivers, and measures anticipated outcomes for patients. The OASIS coordinators will check for compliance with the OASIS data transmission regulation (42 CFR 484.20) (which requires electronic submission of OASIS information to the State), offsite, and report any concerns to the SA surveyors.

2196.1B - Partial Extended Survey.--Is conducted:
(Rev. 1, 05-21-04)

- When standard-level deficiencies are found during the standard survey and it is suspected that a more comprehensive review of the CoPs examined under the

standard survey would determine condition-level rather than standard-level deficiencies; or

- To determine if standard or condition-level deficiencies are present in the CoPs not examined in the standard survey.

2196.1C - Extended Survey
(Rev. 1, 05-21-04)

Is conducted:

- To review and identify the HHA's policies and procedures that produced the substandard care (one or more condition-level deficiency(ies) identified under the standard or partial extended survey; and

- To determine whether the HHA is in compliance with all of the CoPs.

2196.2 - Home Health Functional Assessment Instrument (FAI)

(Rev. 1, 05-21-04)

Exhibit 103 contains the FAI instructions and an example of the 5 Modules and 1 Calendar Worksheet that constitute the FAI. In general, surveyors should use the modules A, B, C and the Calendar Worksheet of the FAI to record individual items of information in a systematic way to determine whether an HHA is furnishing individual care and services in compliance with the regulations. Include identifying information on the FAI official Worksheets to assist in later review.

MODULE A: Use Module A to collect discreet patient-centered medical information to determine the appropriateness of the care or services being furnished. It is not necessary to complete each item for each patient. An option to using Module A is to request the HHA to copy the most current plan of care for each patient in the survey sample (and/or the previous Form CMS-485, if appropriate) that identifies baseline medical information for the attachment to the patient's FAI.

MODULE B: Use only for those patients whose admitting diagnosis(es) or complications of the secondary diagnosis(es) directly affect the patient's potential to meet his or her own activities of daily living (ADLs) and when there is reason to expect that skilled patient care interventions by the HHA will have helped the patient move toward achieving his/her highest maximum potential of functioning. The surveyor records only information that helps compare the progress (or lack of progress) of the patient's functional abilities at two points in time; at admission and at the survey clinical record review. If progress is not being made, determine if intervening events are recorded.

MODULE C: Use Module C for home visit guidance only. It is not necessary to complete each item for each patient because the information needed to determine the

appropriateness of the care or services being furnished to the individual patients varies with each patient situation.

MODULE D: Complete each item in Module D for each patient in the survey sample to record the surveyor's decision about the appropriateness of the HHA's care and services for each individual patient.

MODULE E: Complete each item in Module E to summarize the surveyor or team's decision about the care and services provided by the HHA for all of its patients and to complete the survey process.

CALENDAR WORKSHEET: Use the Calendar Worksheet to determine compliance with 42 CFR Part 484.18(a) and (b) and 42 CFR Part 484.55 or to record any other information that seems appropriate to the patient's specific condition or services provided.

2196.3 - Clinical Laboratory Improvement Amendments

(Rev. 1, 05-21-04)

Regulations implementing the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were published February 28, 1992, and became effective September 1, 1992. Additional changes were published in an update to the CLIA regulations dated January 19, 1993. If the HHA is providing laboratory testing as set forth in 42 CFR Part 493, the SA must request to see the CLIA certificate applicable to the testing being performed, i.e., a Certificate of Waiver, a Certificate for Provider Performed Microscopy Procedures, Certificate of Accreditation, Certificate of Registration or Certificate of Compliance. HHAs holding a Certificate of Waiver are limited to performing only those tests determined to be in the waived category. HHAs holding a Certificate for Provider Performed Microscopy Procedures are limited to performing only those tests determined to be in the Provider Performed Microscopy Procedure Category or in combination with waived tests. All other testing performed by the HHA requires either a Registration Certificate (which allows the performance of such testing until a determination of compliance is made), a Certificate of Accreditation, or a certificate of compliance (issued upon the determination of compliance after an onsite survey). If the facility does not possess the appropriate CLIA certificate, the SA informs the facility that it is in violation of the CLIA law and that it must apply immediately to the SA for the appropriate certificate.

Assisting individuals in administering their own tests, such as finger stick blood glucose testing, is not considered testing subject to the CLIA regulations.

NOTE: Some States have laboratory licensure programs approved by CMS as meeting the CLIA requirements. The laboratories in these States must hold the applicable State license for the level of testing being performed.

2198 - Standard Survey - Structure
(Rev. 1, 05-21-04)

2198A - Components
(Rev. 1, 05-21-04)

Under the standard survey, the surveyor is required to:

- Select and review, to the extent practical, a case-mix, stratified sample of clinical records for individuals receiving items and/or services provided by the HHA; and

- Conduct RN home visits to those patients who have given consent, or family/caretaker consent if the patient is unable to give consent as a result of his or her medical, mental, or emotional problems.

Although the focus of the standard survey is on patients receiving skilled services, non-skilled patients may also be included in the samples for review.

2198B - Activities
(Rev. 1, 05-21-04)

During the standard survey, the surveyor determines the HHA's compliance with:

- Patient rights (42 CFR Part 484.10);

- Release of patient identifiable OASIS information (42 CFR Part 484.11);

- Federal, State, and local laws and regulations, the disclosure of ownership and management information, and accepted professional standards and principles (42 CFR Part 484.12);

- Coordination of patient services (42 CFR Part 484.14(g));

- Acceptance of patients, PoC, and medical supervision (42 CFR 484.18);

- Home health aide services (42 CFR Part 484.36);

- Clinical records (42 CFR Part 484.48); and;

- Comprehensive assessment of patients (42 CFR Part 484.55).

2198C - Applicability
(Rev. 1, 05-21-04)

All HHAs are required to have an unannounced standard survey no later than 36 months after the date of the previous standard survey. Each State must follow CMS' instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. (See §2195.) Periodically, branch locations should be included in, or replace, the unannounced standard survey of a parent HHA or of an HHA subunit with branches. Routinely conduct the recertification survey at a branch location when that location serves more patients than the parent, and visit all locations of an HHA during the survey whenever possible.

The SA conducts a standard survey:

- Of HHAs making initial application for Medicare approval. If the HHA patient census is inadequate to provide the samples necessary (see §2200), include the requirements under 42 CFR Part 484.14 as part of the standard survey. Follow-up in several months, if warranted;

- Within two months after a significant number of complaints about an HHA have been received by the State since the HHA's last survey. Investigate each complaint alleging noncompliance (see §3281); and

- Within two months of an HHA's change in ownership, management, or administration (see 42 CFR Part 484.12(b)) to determine whether the change has resulted in any decline in the quality of care furnished by the HHA (if you believe such a survey is necessary).

The standard survey may not be conducted by an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the HHA being surveyed for compliance with the CoPs, or who has a personal or familial financial interest in the HHA being surveyed. (See §1891(c)(2)(C)(iii)(I-III) of the Act.)

Neither CMS nor the RHHI requires a survey when a new service is added to an approved HHA. The SA directs the HHA to notify the RHHI about the added service. Review the new service at the next scheduled survey unless you receive a complaint about the HHA or you have concerns about the ability of the HHA to provide the service.

2200 - Survey Tasks
(Rev. 1, 05-21-04)

The outcome-oriented survey process for HHAs involves the following six steps:

- Task 1 - Pre-Survey Preparation

- Task 2 - Entrance Interview

- Task 3 - Information Gathering
- Task 4 - Information Analysis
- Task 5 - Exit Conference
- Task 6 - Formation of the Statement of Deficiencies

2200A - Task 1 - Pre-Survey Preparation
(Rev. 1, 05-21-04)

Prior to each survey, review the HHA file (or application, in the case of an initial) in accordance with §2704. Follow §2710, Reviewing Forms at the Beginning of a Survey. Also review the information in the State files relating to the disclosure of information statement made by the HHA (Form CMS-1513). Check this information for accuracy with the information obtained during the course of the survey. In addition, review any complaint data, previous survey data, and reports generated from the OASIS data These reports contain valuable information that may assist you in identifying areas of concern during the survey and possibly identify individuals to be included in the sample selection. Ask the OASIS Educational Coordinator or the OASIS Automation Coordinator for pertinent information regarding compliance with the OASIS CoPs that can be monitored offsite. Available OASIS reports can be generated for specific time periods (e.g., case-mix, adverse event, risk adjusted OBQI reports).

Specifically, using the worksheet in Exhibit 285 conduct a review of the following five OASIS reports:

OBQM Adverse Event Outcome Report

OBQI Outcome Report

OBQI Case Mix Report

Submission Statistics by Agency Report

Error Summary Report by HHA.

2200A1 - OBQM Adverse Event (AE) Outcome Report and Patient Listing
(Rev. 1, 05-21-04)

As part of the pre-survey process, review the most recent quarter (3 months) or whatever time period is necessary to reach at least 60 patients.

Tier 1 AE Outcomes

The threshold for each Tier 1 outcome is **one** patient. Therefore, the surveyor must—

- Identify if any agency patients experienced either of the 2 adverse event outcomes:

  a. Emergent care for injury caused by a fall or accident at home; or

  b. Emergent care for wound infections, deteriorating wound status.

- During the onsite survey, select patient records and home visits that focus on either (or both) outcome(s) identified on the report.

Tier 2 AE Outcomes

There are six Tier 2 AE Outcomes for consideration. The following thresholds must be met for an outcome in Tier 2 to become a focus area:

- There must be patients who experienced the outcome; and

- The HHA's current incidence rate must be equal to or greater than twice the reference rate.

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the report that met the investigation thresholds of equal to or greater than twice the reference value. In addition to providing **areas** for focus during the onsite survey, the AE Patient Listing Report provides surveyors the opportunity of selecting closed records of specific patients under those outcomes meeting the investigation criteria.

If, after working through the Tier 2 AE outcomes, none of the outcome rates are greater than or equal to twice the reference rate, surveyors may optionally focus on other AE outcomes (not listed on the Worksheet) with incidence rates equal to or greater than twice the reference rate.

2200A2 - OBQI Outcome Report

(Rev. 1, 05-21-04)

As part of the pre-survey process, using the Worksheet as a guide for reviewing the HHA's most recent Risk-adjusted and Descriptive Outcome Report, review the report for those outcomes listed on the Worksheet and choose (if possible) 2 outcomes for focus during the onsite survey that have:

- At least 30 eligible cases;

- A large and unfavorable magnitude of difference between the HHA's and the national reference rates (specific thresholds are described for each of the target outcomes on the Worksheet); and

- Statistical significance equal to or less than 0.10 (as depicted by one or two asterisks).

To calculate the percentage point difference between the agency and the reference outcomes, compare the reference percentage point value (found at the end of the "reference" bar) and the agency percentage point value (found at the end of the "current" bar). When looking at "Acute Care Hospitalization," determine if the HHA's outcome is at least 10 **percentage points** higher than the reference value. When looking at the remaining nine outcomes on the worksheet, evaluate whether the agency's outcome is lower than the reference outcome by an amount equal to or greater than the listed threshold.

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the OBQI report meeting the individual investigation thresholds.

If none of the 10 listed outcomes on the Worksheet trigger the selection criteria, another outcome should be selected from the OBQI report that is not on the Worksheet but meets the selection criteria. If there are no statistically significant outcomes that meet the selection criteria, the survey will not focus on an OBQI Outcome.

2200A3 - OBQI Case Mix Report
(Rev. 1, 05-21-04)

The OBQI Case Mix Report identifies the HHA patient population trends to investigate during the onsite survey. As part of the pre-survey process:

- Use the OBQI Case Mix report for the same timeframe as the OBQI Outcome Report;

- Focus on acute conditions and home care diagnoses that are statistically significant and are equal to or greater than 15 percentage points higher than the reference rate;

- Choose up to three conditions or diagnoses that meet the criteria; and

- Select one or two records of patients with diagnoses that meet the criteria for review with or without home visits.

If no conditions or diagnoses trigger the investigation criteria, this will not be an area of focus during the survey.

2200A4 - Submission Statistics by Agency Report
(Rev. 1, 05-21-04)

As part of the pre-survey process, determine whether the HHA:

- Is submitting data less often than monthly; and/or

- Has greater than 20 percent of records rejected in accordance with Worksheet instructions.

If either probe is triggered, investigate compliance with the OASIS transmission requirements (42 CFR 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

2200A5 - Error Summary Report by HHA
(Rev. 1, 05-21-04)

As part of the pre-survey process:

- Focus on four errors listed on the Worksheet--

    1. Error 102, Inconsistent Lock Date – According to the current regulations for OASIS reporting, assessments must be reviewed, corrected as needed, and data- entered and locked within a 7-day period. Investigate further if the HHA's percent of assessments with this error is at or above 20 percent.

    2. Error 262, Inconsistent M0090 date – M0090 is the date the assessment is completed. The recertification assessment must be done on an every 60-day cycle. Investigate if the HHA's percent of assessments with the error is at or above 20 percent.

    3. Error 1003, Inconsistent effective date sequence – This error warns the HHA that the effective date of the assessment it just submitted was earlier than the most current assessment received. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent; and
    4. Error 1002, Inconsistent record sequence – This error warns the HHA that the assessment it just submitted does not logically follow the previous one submitted and may indicate the HHA has missed submitting a record. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent.

- Note whether the error appears on the report **and** meets or exceeds the identified thresholds by checking "Y" or "N" on the Worksheet.

If any of the 4 errors listed on the Worksheet meet the investigation thresholds, further investigate compliance with the applicable OASIS reporting requirements (42 CFR 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

- Effective December 8, 2003, and until further notice, State Survey Agencies (SAs) must not cite any deficiency for an HHA's failure to include the OASIS data set as part of the patient-specific, comprehensive assessment for non-Medicare non-Medicaid patients as required by 42 CFR 484.55.

Initial Certification

Before the initial certification survey is conducted, the SA must have received documentation submitted by the HHA requesting an initial certification survey.

1. Prior to the survey, the SA must have evidence that the HHA:

   - Is operational;

   - Has completed the Medicare Enrollment Application Form CMS-855 and had this form verified by the assigned RHHI;

   - Met the surety bond and capitalization requirements;

   - Is providing nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide);

   - Can demonstrate the operational capability of all facets of its operations;

   - Has successfully completed an OASIS transmission to the State repository; and

   - Has provided care to a minimum of 10 patients requiring skilled care (not required to be Medicare patients). At least 7 of the 10 required patients should be receiving care from the HHA at the time of the initial Medicare survey. If the HHA is located in a medically underserved area, as determined by the CMS RO, the CMS RO may reduce the number of minimum patients from 10 to 5. At least 2 of the 5 required patients should be receiving care from the HHA at the time of the initial Medicare survey.

2. Follow the guidelines in the §2008.A, "Early Surveys of New Providers and Suppliers."

3. Determine that the HHA is in compliance with §1861(o)(4) of the Act and §2180 regarding licensure requirements.

2200B - Task 2 - Entrance Interview
(Rev. 1, 05-21-04)

The entrance interview, which sets the tone for the entire survey, is the critical first stage of the actual survey process. The surveyor must establish rapport with the HHA staff and establish his or her authority as the leader of the survey.

1. Upon arrival at the HHA, complete the following primary activities.

    - Present identification and introduce the survey team members.

    - Request a meeting with appropriate staff based on the organizational characteristics of the HHA. Request a copy of the organization chart, if available.

    - Inform the HHA administrator, director, or supervisor of the purpose of the survey.

    - Ask the administrator to explain the organization, services provided (directly and under arrangement) and the relationship to any corporate structure.

    - Explain the survey process, and estimate the number of days onsite.

    - Be aware that the unannounced survey may be disruptive to the normal daily activities of the HHA.

    - Discuss the extent to which the HHA staff may be involved during the survey.

    - Set up the schedules for any necessary interviews with staff.

    - Request space to work.

Investigate during the survey any discrepancies in information obtained during the entrance interview through a review of source documents and interviews with key staff.

2. Gather the following information during the entrance interview:

    - HHA location (including any branches);

    - Access to clinical records, personnel files, policies, and procedures;

    - Documentation of home health aide training and/or competency evaluations;

    - Information concerning services not provided directly;

- Number of unduplicated patients admitted receiving skilled services during recent 12-month period;

- List or access to names of patients scheduled for a home visit during the survey;

- List of current employees (including name, title);

- CLIA certificate (if applicable);

- Forms to complete: Forms CMS-1513 and CMS-1572;

- Names of key staff (i.e., staff persons most knowledgeable about the home health aides, in-service training, clinical supervision);

- Clinical staff person who will be the primary resource to respond to the surveyor's questions;

- Access to **all** active patient names (Medicare/Medicaid/private pay) receiving skilled services that identifies the start of care (SOC) date, primary diagnosis, and services provided. This will aid in selecting the sample for home visits with record review based on the review of the OBQM and OBQI reports;

- Specific closed records for review from the agency's AE Patient Listing report; and

- If applicable, the HHA's rationale for stating that it is provider-based. (See §2004.)

2200C - Task 3 - Information Gathering
(Rev. 1, 05-21-04)

The information-gathering task is an organized, systematic, and consistent process designed to enable surveyors to make decisions concerning the HHA's compliance with each of the regulatory requirements reviewed during the survey. Action steps involve observation, interviewing, and record review.

2200C1 - Responsibilities include but are not limited to:
(Rev. 1, 05-21-04)

- Reviewing how the HHA performs the comprehensive assessment of patients incorporating the OASIS items;

- Determining if the comprehensive assessment accurately and completely reflects the patient's status for all assessment time points for all patients;

- Reviewing how the HHA determines the appropriate care, services, and treatments for patients to achieve desired health outcomes;

- Reviewing how the HHA delivers care to patients and measures needed and desired patient outcomes;

- Evaluating patient satisfaction with the HHA's services;

- Reviewing how the HHA uses OBQM and OBQI reports available from the OASIS data;

- Reviewing how the HHA's performance has impacted positively and negatively on patients, especially in terms of the care and services that the patients actually experience;

- Determining if the HHA provides care to patients that assists patients to attain and maintain their highest practicable functional capacity;

- Determining if the PoC is consistently implemented, evaluated, reviewed and updated based on the response, outcomes and needs of the patients;

- Selecting a sample for record reviews with home visit;

- Selecting a sample for record reviews without home visit;

- Arranging for and conducting home visits;

- Obtaining patient consent;

- Observing patient care;

- Interviewing staff and patients;

- Reviewing a sample of home health aides files; and

- Reviewing how the HHA complies with CoPs.

2200C2 - Request the following:

- Clinical records;

- Sample of personnel files, and sample of home health aide files;

- Documentation of aide training and/or competency evaluations; and

- Other relevant documents (i.e., policies and procedures) as necessary.

2200C3 - When discussing observations:
(Rev. 1, 05-21-04)

- Use observational skills at all times during the survey and discuss your observations, as appropriate, with team members and HHA personnel;

- Ask pertinent questions to obtain a baseline of information that expands early observations;

- Maintain an open and ongoing dialogue with HHA personnel;

- Give the HHA the opportunity to provide additional information before making compliance decisions;

- Ask staff to describe the usual procedural timeframes for filing pertinent clinical information in the record; and

- Question staff, as appropriate, about incomplete information or inconsistencies in recordings to clarify pertinent observations. Ask that missing information be provided within a reasonable timeframe during the survey.

2200C4 - Clinical Record and Home Visit Selection for Standard Survey
(Rev. 1, 05-21-04)

The surveyor selects, to the extent practical, a case-mix, stratified sample of clinical records of patients who have received or who are currently receiving items and skilled therapeutic services by the HHA under a PoC. "Stratified' means patients selected for a functional assessment are grouped (stratified) based on the primary admitting diagnosis for which the patient is receiving care and treatment from the HHA. "Case-mix" means that the sample includes patients receiving different services from different HHA caregivers (nurse, therapist, social worker, home health aide).

For example, a patient who is admitted to the HHA for treatment of a post-surgical wound is considered in a different stratum from the post-stroke patient. Since HHAs treat patients with a wide range of medical conditions, the review is to encompass patients with varying needs and services. The surveyor may also select some patients for review based on OASIS reports reviewed during pre-survey preparation. The OASIS reports only represent Medicare and Medicaid skilled patients. The sample selected for record review with home visits and record review without home visits should include patients from all payment sources. The patients selected through the use of the OBQM and OBQI reports should not replace the entire stratified sample. Additional current patients should be selected for record review with home visits and record review without home visits.

The surveyor uses the approximate number of unduplicated admissions from all payor sources for skilled services to the HHA (including branches) during the 12 months prior to the survey to determine both the number of clinical record reviews with home visits and the number of clinical record reviews without home visits.

The surveyor uses the HHA's current visit schedule (or plans for visits) during the week that the surveyor(s) is on site to develop the sample for clinical record review with home visits. The sample for clinical record review without home visits may include closed records. The surveyor works with HHA staff to develop, as simply as possible and in the shortest period of time, a survey sample that meets, in its entirety, the following criteria:

- The sample includes a range of primary admitting diagnoses (stratification); and
- The sample represents patients who are receiving various kinds of services (case-mix).

2200C5 - Selecting a Sample of Patients for Clinical Record Review With Home Visits

(Rev. 1, 05-21-04)

Surveyors may conduct home visits to any patient receiving skilled services who grants permission. For clinical record reviews with home visits, the surveyor identifies and selects patients who will receive skilled services at their residence during the remaining days of the survey. Whenever possible, include (at a minimum) at least one patient who is receiving a "high-tech" service. For example, an ideal selection might include (at a minimum) at least one home visit with a registered nurse (RN), one home visit with a therapist, and one home visit with a home health aide. Other home visits could replicate the ideal selection or add more visits of one service based on the HHA's current visit schedule. The surveyor includes patients receiving only home health aide or personal care services to complete the survey sample size, if necessary.

Surveyors must:

- Select one or two patients triggered to be "at risk" of Tier 1 AE outcomes.
- Select one or two patients triggered to be "at risk" for Tier 2 AE outcomes of:
    a. Emergent Care for Improper Medication Administration and Side Effects; and
    b. Emergent care for Hypo/hyperglycemia.
- Select one or two patients with a medical condition relevant to the OBQI outcomes triggered. (For example, if the outcome "Improvement in Urinary Incontinence" is a focus outcome, select one or two patients with urinary incontinence.)

The number of records reviewed, based on the total number of unduplicated admissions requiring skilled services during a recent 12-month period, is as follows:

All Patients Requiring Skilled Services Admitted During Recent 12 Month Period	Record Reviews With Home Visit to Patients Requiring Skilled Services Admitted During Recent 12-Month Period
less than 150	3-5
150-750	5-7
751-1,250	7-10
1,251 or more	25 or more*

***NOTE:** In certain situations, the number of record reviews with home visit may be decreased for HHAs with greater than 1,250 unduplicated admissions for skilled services.

In general, use the lower number in the range for HHAs that historically, in the SA's judgment, have performed well, e.g., have had no conditions out of compliance or few standard level deficiencies in the most recent survey. The range of numbers for home visits contained in the chart suggests minimums. The surveyor conducts more home visits, if necessary.

Therefore, when scheduling the home visits for HHAs with greater than 1,250 admissions, first select a case-mix, stratified subset of 10-12 patients from the original sample of 25 patients. Then review the records and conduct the home visits of these 10-12 patients. If the following three criteria are met, then it is not necessary to complete the remaining record reviews with home visits in the original sample at this point:

- If the findings of the review to this point did not result in your having to conduct a partial extended or extended survey; (See §2196 for guidelines on when to expand the standard survey.)

- If there has been no change in ownership or management of the HHA since the previous State certification survey; and

- If no conditions were found out of compliance during the previous State certification survey. However, if at any time later in the survey process you find it necessary to conduct a partial extended or extended survey, you must complete the remainder of record reviews with home visits from the original sample of 25 patients.

During a survey, patients may be selected for clinical record review with home visit and clinical record review without home visit, regardless of payor source. If the surveyor is unable to draw the required sample size for home visits, increase the clinical record

reviews without home visits by one for each home visit not made. If the HHA patient census is inadequate to provide the samples necessary, include the requirements under 42 CFR Part 484.14 as part of the standard survey.

2200C6 - Selecting Sample of Clinical Records of Patients Who Will Not Receive Home Visit

(Rev. 1, 05-21-04)

Select both closed and active clinical records for review based on the Adverse Event and OBQI outcome(s) triggered for focus and targeted case mix characteristics. If possible, review of closed clinical records identified on the AE Patient Listing report under any triggered outcomes can begin while the HHA obtains the patient roster and home visit schedule.

Select one or two clinical records for review for each Tier 1 AE outcome triggered.

Select one or two clinical records for review for each Tier 2 AE outcome triggered.

NOTE: Patients experiencing more than one Tier1/Tier2 AE outcome are good candidates for clinical record reviews.

For clinical records without home visits the surveyor uses the clinical records of any patients not selected for home visits, regardless of payor source. If additional records are needed to complete the sample size, include records of patients visited 1 to 2 weeks prior to the survey or patients discharged within the same 1 to 2 week period. The number of records reviewed, based on the number of unduplicated admissions of all patients receiving skilled services during a recent 12-month period, is as follows:

All Patients Requiring Skilled Services Admitted During Recent 12-Month Period	Record Reviews of All Patients Requiring Skilled Services Admitted During Recent 12-Month Period
less than 150	8
150-750	10
751-1,250	12
1,251 or more	15 or more

2200C7 - Recording Information

(Rev. 1, 05-21-04)

a. Clinical Record Review

The arrangement and format of clinical records vary among HHAs. To minimize surveyor time spent in reviewing a clinical record and maximize the substantive information that can be obtained, we suggest that the following approach be implemented:

- Review the arrangement and format of one or two records with the HHA staff person recommended by the administrator to answer your questions about how services are organized, delivered, and evaluated. Ask him/her where you are likely to find the information in the clinical record.

- Review the most recent PoC for the primary admitting diagnosis, and the goals to be accomplished by the care.

- Determine if the PoC is current and has been appropriately signed and dated by the physician in compliance with the HHA's policies and procedures. Also, determine if verbal orders have been recorded to initiate appropriate professional services for the patient until the written PoC is received from the physician.

- Determine if the comprehensive assessment accurately reflects the patient's status.

- Evaluate the current status of the patient as reflected in the assessment, PoC, and visit notes.

- Verify that drugs and treatments are provided according to a physician's order and that all drugs have been reviewed by the HHA for potential adverse effects and drug reactions.

- Review the PoC to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs.

- Review the timeliness of services provided to the patient.

- Evaluate the HHA's ability to coordinate care and services.

- Review the patient's progress toward the achievement of desired outcomes.

- Review the RN's initial assessment and a sample of clinical notations by all personnel providing services. Determine if the comprehensive assessment, the PoC and the frequency of visits are clinically congruent or complementary. Did

interventions follow the PoC? Were clinical notes specific to changes in the patient's status?

- Based on the initial assessment and current clinical notes, determine if the patient's medical situation, drug regimen and functional abilities have progressed in relation to the specific care that has been provided. If the patient's clinical and functional abilities have not progressed, have intervening events been recorded appropriately?

- Determine how the HHA ensures coordination of services among and between personnel providing services. What evidence do you find in the clinical record(s) that this is occurring?

- Determine if home health aide recordings document the individual status of the patient. Also, determine if supervisory visits are being made.

- Determine if changes in the patient's medical condition are reported to the physician and recorded, including documentation of verbal orders with written confirmation.

- Determine if the patient's continuation of services or discharge seems appropriate at the time of record review.

- If information cannot be found or cannot be interpreted or integrated, ask the HHA staff to either find the information or help you understand its content.

- Complete Module D immediately after the home visit and/or clinical record review is completed.

b. Compete Surveyor Summary, Module E

If the surveyor determines that the patient care items and services provided by the HHA and reviewed in the standard survey do not pose an immediate and serious threat to the health and safety of its patients, the surveyor chooses one of the three options in the Surveyor Summary block, Module E, to determine what, if any, further survey action to take.

The surveyors record their determination in item 23 of Form CMS-1572(b) (see Exhibit 14D), and select the appropriate action according to the following choices:

- Based on the evaluation of the HHA's compliance with the requirements reviewed as the standard survey, there is no evidence of need for a partial extended or extended survey, the survey is complete Record any standard-level deficiencies identified during the standard survey and request a PoC according to CMS procedures.

- If it is necessary to conduct a partial extended survey and no further deficiencies are found, or if only more standard-level deficiencies are found, the survey is complete. The surveyor records any further deficiencies and requests a PoC according to CMS procedures.

c. Recording Findings From Partial Extended or Extended Surveys

The surveyor uses the HHA interpretive guidelines (see Appendix B) to conduct partial extended and extended surveys to determine compliance with HHA requirements that are not included in the standard survey. The surveyor uses ASPEN or Form CMS-1572 to record deficiencies found as a result of conducting a partial extended survey or extended survey. If either of these surveys include more clinical record reviews with home visits or clinical record reviews without home visits, use the appropriate FAI Modules for gathering and recording information. When conducting a partial extended or extended survey, the surveyor follows the instructions in §2700 as applicable to HHAs.

NOTE: An HHA may, at the discretion of the SA, be subject to an extended or partial extended survey regardless of the findings of the standard survey.

2200C8 - Conducting Home Visits

(Rev. 1, 05-21-04)

a. Prior to Making Home Visits

The surveyor visits patient homes or other places of residence only when patients have given prior consent for the visit. Patient participation is strictly voluntary. Home visits may be made before or after reviewing a patient's clinical record. It is preferable to review the comprehensive assessment and PoC before meeting the patient since this may assist you in making appropriate observations and asking pertinent questions during the home visit.

It is important to contact the patient before you arrive at the home or place of residence, if possible, because the first onsite contact may be intimidating to the patient or may generate some fear that would interfere with access to the patient's home or the quality of the interview. In most situations, the HHA representative who provides care or services should contact the patient/family/caretaker to request permission and make the arrangements for the home visit. However, you may choose to contact the patient/family/caretaker directly.

Be sure that the HHA representative explains clearly to the patient/family/caretaker that the permission for the RN surveyor home visit is voluntary and that refusal to consent to the home visit will not affect his or her Medicaid/Medicare, or other health benefits.

If a patient refuses to have the RN surveyor accompany the HHA representative, select an alternate patient care situation from the sample. A home visit is more effective in

assessing the scope and quality of care being provided if the surveyor is able to observe how HHA personnel implement one or more parts of the patient's PoC. There may be circumstances, however, that should be reviewed during a home visit without the HHA representative being present. If you believe that the HHA representative is not representing the purpose of the visit fairly or appears reluctant to contact the patient/families in the sample, or if you have suspicions or concerns about the care being provided, you may contact the patient/family/caretaker directly to request permission to make the home visit by yourself.

b. Conducting Visit at Home or Place of Residence

When the surveyor arrives at the home or other place of residence, he/she explains that the purpose of the visit is to ensure that care being provided by the HHA meets the health and safety standards of the Medicare program and is done in accordance with the PoC ordered by his or her physician. The surveyor asks the patient to sign a Consent for Home Visit Form (see Exhibit 104), and leaves a copy of the signed consent form with the patient and a copy of signed consent form is filed in the patient's clinical record. Also, the surveyor maintains a copy of the consent statement in the survey file. A Spanish version of the Consent for Home Visit Form is also available.

The surveyor must be continuously aware that as a guest in a patient's home or place of residence, courtesy, common sense, and sensitivity to the importance of an individual's own environment is absolutely essential regardless of the condition of the home.

The surveyor should observe, but not interfere with, the delivery of care or the interaction between the HHA representative and the individual patient/family/caretaker.

Prior to interviewing the patient/family/caretaker, the surveyor reassures them that any discussion is voluntary and refusal to participate will not affect his or her Medicare/Medicaid or other health benefits, they may be entitled to.

c. Discontinuing Interview

Discontinue the interview if:

The patient shows signs of being uncomfortable or seems reluctant to talk, and if, after asking the patient, he or she says they would rather discontinue the discussion;

- The patient appears tired, overly concerned, agitated, etc., and would like to end the interview, or, if in your judgment, it appears to be in the patient's best interest to end the interview; or

- Conditions in the patient' home, such as safety factors, perceptions of intimidation, etc., are of concern to you or the HHA representative.

2200D - Task 4 - Information Analysis

(Rev. 1, 05-21-04)

The information analysis process requires surveyors to review the information gathered during the survey process and to make judgments about the compliance of the HHA. Onsite compliance decisions must not be based solely on OASIS data. The OASIS reports are simply a tool to be used to help guide the onsite survey and identify areas for additional investigation, not to make quality of care determinations. All aspects of patient care must be evaluated. Additional follow-up activities and investigation through record reviews, home visit observations and interviews must substantiate and support any findings of non-compliance with the conditions of participation. When analyzing information and making determinations about the importance of the incidents, the following guidance should be helpful:

Analyze findings relative to each requirement for:

- The effect or potential effect on the patient care outcomes;
- The degree of severity;
- The frequency of occurrence; and
- The impact on the delivery of services.

An isolated incident that has little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a CoP may be considered out of compliance for one or more deficiencies, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect patients. Evaluation of whether a finding constitutes a deficiency, and whether a condition-level deficiency exists must not be made until all necessary information has been collected.

2200E - Task 5 - Exit Conference

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Following a standard, partial extended, and/or extended survey, the surveyor conducts an exit conference in accordance with §2724. The purpose of the exit conference is to inform the HHA staff of the observations and preliminary findings of the survey.

Information recorded on the component parts of the FAIs or other comments recorded on Form CMS-1572 serve as the surveyor's official worksheets. They are not to be given to or copied by HHA staff.

Follow these guidelines during the exit conference:

- Clarify the names and positions of all HHA personnel or other individuals attending the meeting.

- Summarize the facts of the onsite evaluation (team size, composition, days onsite, the sample size for record review and home visits) to set the tone for understanding the overall recommendations that the SA will make to CMS regarding compliance determinations.

- Present findings regarding citations of deficient practice(s) in a straightforward, understandable way, and in a clear logical sequence. Offer examples to support the findings as appropriate.

- Offer the HHA the opportunity to ask questions regarding the findings or provide further pertinent information for the surveyors to consider offsite prior to making formal citation recommendations to CMS on Form CMS-2567.

- Respond to any HHA procedural questions with timely and accurate survey process information (i.e., recertification status: the timeframe for receiving Form CMS-2567 and submitting a PoC to the SA in response to the written citations). Clarify any areas for which further deficiency citations may be made offsite after further analysis with team members or the SA supervisor.

- Provide instructions and timeframe necessary for submitting a PoC as referenced in §2724.

- Describe the procedures that are not in compliance with regulations and the findings that substantiate the deficiencies, identifying specific regulatory references in response to questions raised by staff.

Present Form CMS-2567 onsite or in accordance with the SA's policy, but no later than 10 working days after the exit conference.

NOTE: Surveyors should refer to §2724 for additional information on the exit conference, presence of counsel, taping of the conference, and situations that would justify refusal to conduct or continue an exit conference.

2200F - Task 6 - Formation of the Statement of Deficiencies

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspects of each requirement not met. The §2728 provides detailed instructions on the effective completion of Form CMS-2567.

2202 - Outcome and Assessment Information Set (Oasis) Requirements

(Rev. 1, 05-21-04)

The home health regulations now require that each patient receive from the HHA a patient-specific, comprehensive assessment, and that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are detailed in the January 25, 1999, "Federal Register" (64 FR 3764) and at 42 CFR Part 484. This regulation is referred to as the "collection regulation."

The regulations also require that OASIS data be electronically transmitted to the SA or CMS OASIS contractor. These requirements are detailed in the January 25, 1999, "Federal Register" (64 FR 3748) and at 42 CFR Part 484. This regulation is referred to as the "reporting regulation."

The CMS uses the data to achieve broad-based improvements in the quality of care furnished, through measurement of that care, as well as to maintain a home health prospective payment system.

In addition to requiring the reporting of OASIS data, the OASIS regulations require HHAs to maintain privacy of their OASIS data. Regulations concerning State survey, certification, and enforcement responsibilities are found at 42 CFR Part 488.68.

In a "Federal Register" notice published June 18, 1999,(64 FR 32984), CMS re-established the effective date for the mandatory use, collection, encoding, and transmission of OASIS data for all Medicare/Medicaid patients receiving skilled services. Mandatory collection and transmission of OASIS data were delayed shortly after the initial publication of the OASIS regulations in order to ensure the proper balance between preserving individual privacy and fulfilling the statutory requirement to improve quality and pay providers fairly.

Effective July 19, 1999, all HHAs participating in the Medicare/Medicaid program have been required to comply with the comprehensive assessment and OASIS reporting regulations.

NOTE: For patients receiving personal care only services, regardless of payor source, the requirements regarding the comprehensive assessment and OASIS reporting have been delayed until further notice.

- The collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended on December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific

comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

- HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

2202.1 - OASIS Related Definitions

(Rev. 1, 05-21-04)

OASIS - Scientifically tested data items developed for the purpose of measuring outcomes (and patient risk factors that affect outcomes) for HHA patients. These data items alone do not constitute a comprehensive assessment; they must be collected as part of the assessment process at various time points during a patient's admission to an HHA.

- **Comprehensive Assessment -** An assessment of a patient's condition that accurately and completely reflects the patient's current health status at the time of the evaluation. This assessment must identify the patient's continuing need for home care and must meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. An HHA must include the collection of specific OASIS data items at specific time points during a patient's admission as part of its comprehensive assessment process for all Medicare and Medicaid patients. The specific OASIS items associated with each assessment time point are summarized in each version of the OASIS data set. The required OASIS data set and its time point related versions include (1) Start of Care/Resumption of Care, (2) Follow-up, (3) Transfer, and (4) Discharge. HHAs should use the most current version of the OASIS. The most current version of OASIS is available on the OASIS Web site.

Encode - To enter OASIS data into a computer using the Home Assessment and Validation Entry (HAVEN) software (provided by CMS) or other HAVEN-like software (developed by private vendors). HAVEN-like software must meet CMS' data and edit specification requirements.

Encryption - A system to translate plain text into scrambled code. Encryption offers a higher level of security when electronically transmitting information. The sender "locks" the data before transmitting. The receiver "unlocks" the data upon receipt.

HAVEN - A software program provided by CMS, free of charge, for use by HHAs to encode their OASIS data and save as electronic files for electronic transmission to the State survey agency. The HAVEN software automatically applies date range and consistency checks according to CMS' published data specifications, which serve as an electronic safety net to preclude the transmission of erroneous or inconsistent information.

Header Record - Contains basic information that identifies the HHA submitting OASIS data, as well as, contact persons and telephone numbers to be used in the event the file is in error.

Initial Assessment - The HHA's first visit to the patient after referral. In the absence of a specified start of care date, the initial visit is the first visit made to the patient within 48 hours of the referral. If the physician specifies a particular start of care date, then the initial visit is the date specified by the physician. In accordance with the regulations, the initial visit must be made by a registered nurse or, for therapy-only cases, a qualified therapist.

Incorporate/Integrate - Incorporating/integrating the OASIS data items into an agency's assessment process means replacing similar questions on the agency's existing assessment tool with the corresponding OASIS data items. Agencies must merge the OASIS data items into their existing assessment process rather than simply appending them without considering which OASIS items could replace similar items on the agency's assessment tool. Simply appending the OASIS items adds time to the assessment process and renders it burdensome and duplicative. Since the OASIS items are not intended to constitute a complete comprehensive assessment, agencies should gather other pertinent assessment information not included in the OASIS data items in order to create a comprehensive assessment. Except as required to meet other Federal, State, or accreditation standards, agencies are at liberty to determine what other information they require as part of the comprehensive assessment.

Late Assessment - An assessment completed after the specific time frames defined in the regulations.

Lock - To review, edit, and finalize encoded OASIS data in order to create a file that is transmitted to the SA. Once a data record is locked, no further edits are permitted prior to submission of the data record.

Masking - A term used to describe software that conceals individually identifiable data elements. When required, HHAs will mask these data elements prior to transmission and keep the masked identifiers and the original data in their records. HAVEN currently

automatically masks certain individually identifiable data elements on non-Medicare and non-Medicaid assessments that HHAs may voluntarily submit to the SA.

Medicare Data Communications Network (MDCN) - A private communications network CMS purchased to ensure the security of OASIS and Minimum Data Set (MDS) data transmissions to the State. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. In addition to increased security, another benefit of the MDCN is that it is provided at no cost to the HHAs. HHAs may also apply for an MDCN User ID and password for each of their branches for direct transmissions from their branches. Use of the MDCN allows for all data submitted to our OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the MDCN, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the MDCN and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

Outcome - Changes in a patient's health status between two or more time points

Outcome-Based Quality Improvement (OBQI) - Performance improvement based on outcome measurement and reporting.

Outcome-Based Quality Monitoring (OBQM) Reports - The first two of three outcome reports based on OASIS data. The OBQM reports include the case mix and adverse event outcome reports.

Overdue OASIS - OASIS assessments not received by the OASIS State System within the specific time frames defined by the regulations. (See also Late Assessment.)

Reason For Assessment (RFA) - Reason for conducting the assessment, e.g., Start of Care (SOC), Resumption of Care (ROC), Follow-Up found in M0100.

ROC - The day that care resumes after an inpatient stay. The ROC is to be done within 48 hours of the patient's return home. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient's chart for future reference.

Significant Change in Condition (SCIC) - A SCIC is defined as a significant change in the patient's condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient's plan of care. This provides an opportunity for HHAs under PPS to adjust resource levels during a given 60-day episode to account for an unanticipated

change in the patient's condition that requires a change in case mix level. The SCIC adjustment is the proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode. The SCIC relates to the OASIS data set for ROC (if the SCIC follows an inpatient stay) and "other" Follow-Up (if the SCIC does not involve an inpatient stay).

SOC - The day care begins after the referral is received. SOC currently relates to the "first billable visit." The "first billable visit" approach was selected largely because of the Medicare payment requirements and the fact that the first billable visit defines SOC and start of the episode for Medicare purposes.

Time Points - Specific times during an episode of care when collection of OASIS data items is required as part of a comprehensive assessment. They are SOC, ROC, Follow-Up, transfer to an inpatient facility, and discharge (including death).

Trailer Record - Indicates the end of the submission file. The trailer record includes a count of the total records in the file, including the header and trailer records.

2202.2 - History of OASIS

(Rev. 1, 05-21-04)

The OASIS is a group of data items developed, tested, and refined over the past decade for the purpose of enabling the systematic measurement of HHA patient care outcomes. Initially, the OASIS was a 79-item data set first published in 1994 by the Center for Health Services and Policy Research at the University of Colorado. Over the years, it has been modified as a result of input from a variety of home care experts, including representatives of all home health care disciplines. Future modifications to the OASIS are expected as we learn more about outcome measurement as well as determine what information would best serve the continued maintenance of a case-mix adjusted home health PPS.

Relative to OASIS, the definition of outcomes is very specific: outcomes measure changes in a patient's health status between two or more time points. The data are collected at specific time points following a patient's admission to an HHA to determine whether appropriate progress toward desired outcomes is being achieved. These data items must be incorporated into the agency's overall patient assessment process as OASIS was not developed to be a complete comprehensive assessment instrument. HHAs will find it necessary to integrate the OASIS items into their own process in order to comprehensively assess the health status and care needs of their own patient population. Some points to remember about the integration of OASIS data items into an HHA's assessment process:

2202.2A - Current Version of OASIS

(Rev. 1, 05-21-04)

The most current version of OASIS is found on the OASIS Web site at http://www.cms.hhs.gov/oasis/. In the OASIS User's Manual, also found on the OASIS Web site, Appendix B lists the current OASIS items to be used at each assessment time point as separate documents.

2202.2B - OASIS as Part of the HHA's Comprehensive Assessment

(Rev. 1, 05-21-04)

OASIS data items are not meant to be the only items included in an agency's assessment process for Medicare and Medicaid patients. They are standardized assessment items that must be incorporated into an agency's own existing assessment policies process. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in Appendix C: Sample Clinical Records Incorporating OASIS B-1 Data Set, in the OASIS User's Manual. For a therapy-only case, the comprehensive assessment should include OASIS data items as well as other assessment data items the agency currently collects for therapy-only cases.

2202.2C - Incorporation of OASIS Data Items Into the Comprehensive Assessment

(Rev. 1, 05-21-04)

In accordance with the regulations, agencies MUST incorporate the language of OASIS data items **exactly** as they are written into their own assessment process. Agencies are expected to replace similar items/questions on their current assessment as opposed to simply adding the OASIS items at the end of their existing assessment tool. For agencies electronically collecting assessment data using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, capitalizing these words is acceptable. It is also recommended that HHAs include the data set numbers (M00 numbers) when incorporating the OASIS. In this way, the clinician will know that the M00 labeled items are items that MUST be assessed, completed, and reported. This will minimize delays in encoding due to incomplete OASIS data items. Agencies may wish to incorporate the assessment categories (e.g., Activities of Daily Living (ADLs)/Instrumental Activities of Daily Living (IADLs), Medications, etc.) into their own assessment process in a different order than presented on the OASIS form. While HHAs are encouraged to integrate the OASIS data items into their own assessment instrument in the sequence presented on the OASIS form for efficiency in data entry, they are not precluded from doing so in a sequence other than that presented on the OASIS form. However, this is not recommended because of the skip patterns built into the OASIS form.

2202.2D - Copyright Release

(Rev. 1, 05-21-04)

Appendix B of the OASIS User's Manual contains a copyright release for the OASIS. While OASIS may not be copyrighted by any other party, the copyright release document grants the right for home care providers and related organizations, businesses, and individuals to copy, reprint and use the OASIS at no cost, as long as acknowledgment of authorship is noted. A sample acknowledgment is included in the release document.

2202.3 - Applicability

(Rev. 1, 05-21-04)

2202.3A - Medicare and Medicaid Patients

(Rev. 1, 05-21-04)

In general, the comprehensive assessment and reporting regulations apply to any HHA required to meet the Medicare CoPs for any reason and are applied to all patients of that HHA unless otherwise specified. This includes Medicare, Medicaid, Medicare and Medicaid Managed Care, and private pay patients served by the agency. It also includes Medicaid waiver and State plan patients to the extent they do not fall into one of the exception categories listed below, and are required by the State to meet Medicare CoPs. HHAs providing services under Medicaid's home health benefit must meet the CoPs for Medicare, as specified at 42 CFR 440.70(d). As such, HHAs servicing only Medicaid patients (Medicaid-only HHAs) must meet Medicare CoPs, including the comprehensive assessment and OASIS reporting requirements.

Health maintenance organizations serving Medicare/Medicaid patients can either provide home health services themselves or can contract out for those services. If they provide home health services themselves, they must meet the Medicare home health CoPs. If they contract out for home health services, they must contract with a Medicare-approved HHA in order to serve Medicare/Medicaid patients. (See 42 CFR 417.416 and §2194.)

The HHA's requirement to conduct comprehensive assessments that **include** OASIS data items applies to each patient of the agency receiving home health services with certain exceptions:

- Patients under the age of 18;
- Patients receiving maternity services;
- Patients receiving housekeeping or chore services only; and
- Patients receiving personal care services only.

- Patients for whom Medicare or Medicaid insurance is not billed.

The comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source is not applicable.

2202.3B - OASIS and the Medicare Home Health Benefit

(Rev. 1, 05-21-04)

The comprehensive assessment and OASIS data collection requirements apply to Medicare beneficiaries as described below:

- Medicare beneficiaries, using the Medicare home health benefit provided under either Part A, Part B, or Part C;

- Medicare beneficiaries who require therapy services provided outside the home for special equipment needs, and who are using the Medicare home health benefit.

If a Medicare beneficiary is under a home health plan of care, all therapy services, that is physical therapy, occupational therapy, speech language pathology (PT, OT, SLP), delivered under the home health benefit whether they are furnished directly by the HHA or under arrangement on behalf of the HHA are bundled into the PPS payment rate as part of the consolidated billing requirements.

The consolidated billing governs Medicare home health PPS effective October 1, 2000 and requires that payment for home health services (including medical supplies described in §1861(m)(5) of the Act, but excluding DME to the extent provided for in §1861(m)(5)) furnished to an individual who (at the time the item or service was furnished) is under a plan of care of a HHA, be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or under any other contracting or consulting arrangement, or otherwise). The services included in the consolidated billing governing home health PPS are:

- Part-time or intermittent skilled nursing services;

- Part-time or intermittent home health aide services;

- Physical therapy; Speech-language pathology services;

- Occupational therapy;

- Medical social services;

- Routine and non-routine medical supplies;

- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals; and

- Home health services defined in §1861(m) provided under arrangement at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home or are furnished while the patient is at the facility to receive such services.

If a Medicare beneficiary under a home health plan of care is receiving therapy services from another provider (either an inpatient or outpatient provider) under arrangement made by the HHA as part of the home health benefit simply because the required equipment cannot be made available at the patient's home, the Medicare CoPs apply, including the comprehensive assessment and collection and reporting of OASIS data by the HHA.

1. Medicare+Choice Organization (MCO)

Medicare beneficiaries who elect to have Medicare services provided by an MCO are entitled to all the Medicare-covered services that are available to beneficiaries residing in the MCO's geographic area. MCOs that contract with Medicare to furnish HHA services may provide such services either directly or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 422.112). If an MCO provides home health services directly as an integral part of the MCO, it is referred to as an MCO-operated HHA, and the MCO itself must meet the HHA CoPs. MCO beneficiaries covered under Medicare Part C are not subject to the coverage rules for PPS, including the consolidated billing requirements.

2. Medicaid Home Health Programs/Medicaid Waiver Programs

The comprehensive assessment regulations apply to HHAs that are required to meet the Medicare home health CoP. An HHA that currently must meet the Medicare CoP under Federal and/or State law must meet the Medicare CoP related to OASIS and comprehensive assessment and reporting. If an HHA provides skilled services to individuals under Medicaid, then OASIS applies. If the patient is not receiving skilled nursing, physical therapy, occupational therapy, or speech language pathology services, then OASIS does not apply. The requirement to collect OASIS on patients receiving only personal care services has been delayed until further notice.

3. Medicare Hospice Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to any individual receiving hospice services from a Medicare-approved hospice. A hospice patient may receive covered home health services for a condition unrelated to the treatment of the terminal condition for which hospice care was elected. This type of patient would be subject to the regulations governing the HHA services, including OASIS collection and reporting.

4. Outpatient Therapy Benefit

If a Medicare beneficiary not under a home health plan of care is receiving therapy services under the Medicare Part B outpatient benefit from another Medicare provider, the OASIS collection and reporting requirements do not apply.

5. SNF or Inpatient Hospital Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to Medicare beneficiaries who are inpatients at a SNF or a hospital because these services are not considered home health services and the OASIS comprehensive assessment does not need to be conducted. The MDS is required in certified skilled nursing facilities.

The following table summarizes the type of Medicare/Medicaid service and the application of the Federal OASIS requirements:

Type of Medicare Service	**Further Description**	**Application of OASIS**
Home Health Benefit	Part A	Yes
Home Health Benefit	Part B	Yes
Home Health Benefit	Terminal Care	Yes
Home Health Benefit	Therapy services provided either directly or under arrangement while under a home health PoC during an open episode.	Yes
Medicare + Choice Home Health Care	The selected HHA must be Medicare approved	Yes
Medicaid Home Health Benefit	Skilled services provided including expanded home health services, that are skilled, provided under a Home and Community–based Waiver	Yes
Medicaid Home Health Benefit	Waiver service or home health aide services only provided without skilled services	No
Medicare Hospice Benefit	Inpatient or at home	No
Outpatient Therapy Benefit (patient not under a home health plan of care)	Provided in a clinic, rehabilitation agency, a public health agency or other provider of services	No
Skilled Nursing Facility, Hospital	Inpatient services	No

The guidance above applies to all accredited HHAs that participate in Medicare and to HHAs that are required to meet the Medicare CoP, including Medicaid HHAs.

2202.3C - Non-Medicare/Non-Medicaid Patients

(Rev. 1, 05-21-04)

The collection, encoding, and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is temporarily suspended. While HHAs are not required to collect OASIS for non-Medicare/non-Medicaid patients, HHAs may continue to collect OASIS data for their own use. HHAs are not required to submit their OASIS data on non-Medicare and non-Medicaid patients but they may do so as a system to mask their identity has been developed and is accomplished automatically using the current HAVEN software. HHAs must meet all other requirements of the comprehensive assessment regulation including conducting SOC comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services.

2202.3D - Skilled Versus Nonskilled Care

(Rev. 1, 05-21-04)

Until the comprehensive assessment and reporting requirement resumes for all patients, regardless of type of care provided, the following definitions apply for determining skilled versus non-skilled care for comprehensive assessment purposes only:

- Skilled Services for Medicare Patients - The provision of skilled service is a pre-condition for Medicare payment for home health care. Therefore, all patients receiving Medicare (traditional) home health services are, by definition, receiving skilled care.

- Skilled Services for Non-Medicare Patients - For comprehensive assessment purposes, skilled services are services which can only be provided by a registered nurse (RN) (or a licensed practical nurse under the supervision of an RN), a physical therapist (PT), occupational therapist (OT), or a speech language pathologist (SLP), licensed by the State. Most States define the kind of care that is allowed by these practitioners under State practice acts.

The former requirement to conduct an initial evaluation of a patient is expanded in the comprehensive assessment regulations. The regulations now require that, in addition to an initial evaluation, the agency must also conduct a comprehensive assessment of a patient with updates at certain time points. These updates include different combinations of OASIS data items. An agency that currently must meet the Medicare CoPs under Federal and/or State law will need to meet the comprehensive assessment and OASIS encoding and reporting CoPs and apply them to each patient of the agency for whom home health services are rendered, with the exceptions listed in A. above.

2202.3E - Agencies Serving Medicaid Waiver and State Plan Patients

(Rev. 1, 05-21-04)

If home care is provided by an entity required to meet the Medicare CoPs for any reason, then the entity must apply all the requirements of the CoPs, including the comprehensive assessment and OASIS data reporting requirements, to all patients of the agency, including patients treated under a Medicaid waiver or State plan, as applicable. The same exceptions apply as listed in A. above, i.e., patients under the age of 18; patients receiving maternity services; patients receiving housekeeping or chore services only; and until sometime in the future, patients receiving personal care services only.

If home care is provided by an entity that is not required to meet the Medicare CoPs, then the provider must comply with only those requirements imposed under State or local law. In this case if the provider treats patients under a Medicaid waiver or State plan, then none of the Medicare CoPs for HHAs, including the comprehensive assessment and OASIS data reporting requirements, apply. See §2183 for information on separate entities.

2202.3F - Patients Turning 18

(Rev. 1, 05-21-04)

A patient who is under age 18 and turns 18 while under the care of an HHA is to receive a comprehensive assessment (including OASIS, if Medicare or Medicaid is billed) at the next appropriate time point. Any assessments due under the regulations at the time the patient turns 18 would be conducted, including the collection and reporting of OASIS data, if Medicare or Medicaid is billed.

EXAMPLE

If on 1/5/00 a patient under the care of the agency turns 18 and is transferred to an inpatient facility on or after 1/5/00, a transfer assessment with the corresponding OASIS data items must be collected. If the patient was discharged on his/her 18th birthday, a discharge assessment with the corresponding OASIS data items must be collected.

From the day the patient turns 18, any assessment required per the regulations at the next particular time point is required. Agencies are not expected to collect and report start of care OASIS data on patients admitted to the agency prior to turning 18.

2202.3G - Patients Receiving Maternity Services

(Rev. 1, 05-21-04)

The HHA should not collect data on patients receiving maternity services, i.e., prenatal, antepartum, and postpartum. The patient is not exempt from OASIS data collection if under the care of a physician for a condition unrelated to pregnancy or delivery.

2202.4 - Comprehensive Assessment and OASIS Reporting

(Rev. 1, 05-21-04)

Effective July 19, 1999, and revised December 8, 2003, all HHAs participating in the Medicare/Medicaid program are required to comply with the comprehensive assessment and OASIS reporting regulations as summarized in the following chart.

PATIENT CLASSIFICATION	**COLLECT**	**ENCODE**	**TRANSMIT**
SKILLED Medicare (traditional fee-for service) Medicare (HMO/Managed Care) Medicaid (traditional fee-for-service) Medicaid (HMO/Managed Care)	7/19/99	7/19/99	8/24/99
SKILLED Non-Medicare/Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	7/19/99 Temporary Suspension effective 12/08/03	Delayed	Delayed
PERSONAL CARE ONLY Medicaid (traditional fee-for service) Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	Delayed	Delayed	Delayed
EXCLUDED Patients under age 18; Patients receiving pre & post partum maternity services; Patients receiving only chore and housekeeping services	Excluded	Excluded	Excluded

2202.4A - Comprehensive Assessment and OASIS Collection

(Rev. 1, 05-21-04)

The comprehensive assessment regulations require a comprehensive assessment (that includes certain OASIS data items) be conducted at specific time points during a patient's admission. Those specific times are:

1. SOC

After admission to the HHA, the SOC comprehensive assessment should be completed in a timely manner consistent with the patient's immediate needs but no later than 5 calendar days after the SOC.

2. ROC

The comprehensive assessment is completed within 48 hours of the patient's return to the place of residence after an inpatient admission of 24 hours or more for any reason other than diagnostic tests. This applies when the patient was not discharged from the HHA during the inpatient admission. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient's chart for future reference.

3. Follow-Up - The comprehensive assessment that is performed at the end of the current 60-day period. This assessment must be performed within the last 5 days of the current 60-day episode. For example:

Start of Care	Certification Period	Follow-Up Assessment Due
1/15/2004	1/15/2004 - 3/14/2004	3/10/2004 - 3/14/2004
1/15/2004	3/15/2004 - 5/13/2004	5/09/2004 - 5/13/2004
1/15/2004	5/14/2004 - 7/12/2004	7/08/2004 - 7/12/2004

4. Transfer to an Inpatient Facility

An assessment update is performed when a patient is transferred to an inpatient facility for 24 hours or more for any reason except diagnostic testing, regardless of whether the patient is discharged from the HHA at that time. The update must be completed within 48 hours of the patient's transfer to the inpatient facility or within 48 hours after the HHA becomes aware of the transfer and includes a limited number of OASIS items.

5. Discharge

The comprehensive assessment is performed when a patient is discharged from home care. These updates must be completed within 48 hours of the discharge/death or within 48 hours after the HHA becomes aware of the discharge/death.

2202.4B - OASIS Encoding and Locking

(Rev. 1, 05-21-04)

HHAs should use HAVEN or HAVEN-like software to encode or enter OASIS data into their computers. HAVEN will accommodate data entry of OASIS items from all required time points. Regardless of the time point, OASIS data items should be encoded, checked for errors, and locked within 7 days of collection using HAVEN or HAVEN-like software, i.e., made transmission-ready.

1. Availability of HAVEN

The HAVEN software is available for downloading free of charge from the OASIS Web site. HAVEN is also available on compact disk (CD) at no charge. HHAs can request the HAVEN CD by calling the HAVEN help line at: 1-877-201-4721. Specific information describing how to operate the HAVEN software is in the OASIS User's Manual, described below. Each SA is mailed one copy of the current HAVEN software on CD.

2. Errors and Warnings in Encoding and Locking

HHAs may experience two types of messages at completion of data entry.

a. Error Message.

If the HHA uses HAVEN for data entry, an error message may occur if a mandatory field is left blank. The HHA will receive an error that the field must be filled in before the assessment can be marked as complete. HHAs should correct their errors before an assessment may be locked and exported to the OASIS Data Management System. Along with the error message is the name of the window tab where the error was detected.

b. Warning Message

If the HHA uses HAVEN for data entry, a warning message may occur if timing criteria for date fields do not match OASIS data specifications. These messages are informational only and do not preclude an HHA's assessment from being exported. Along with the warning message is an explanation of that message and direction on where the discrepancy was detected.

2202.4C - OASIS Reporting

(Rev. 1, 05-21-04)

1. HHA Submissions

At least once a month, HHAs will retrieve all of their locked data from the previous month that has not yet been transmitted and send it to the SA (or other designated location) using the Medicare Data Communications Network. HHAs may transmit their OASIS data more frequently if they choose but must submit it no later than the last day of the month following the month in which it was locked. Data received outside of these time frames is considered overdue. Specific information describing how HHAs are to transmit OASIS data to the SA is in the OASIS User's Manual.

2. Errors and Warnings in OASIS Reporting

When submitting OASIS records, a fatal error message may occur if the HHA's data record layout does not follow OASIS data specifications. This message should not occur if the HHA is using the HAVEN software to encode the OASIS items.

3. SA Access

In States where the non-long term care agency is in a location separate from the OASIS State System (where the MDS Data System resides and is not under the direct jurisdiction of the home health survey agency), CMS provides access to the OASIS State System by installing a computer work station at the home health survey agency address to link to the OASIS State System.

The CMS will provide additional support to the SA to access and operate the off-site server by providing appropriate software (e.g., PC Anywhere software), and technical assistance from CMS and the CMS OASIS contractors.

2202.5 - Outcome-Based Quality Improvement (OBQI)

(Rev. 1, 05-21-04)

OBQI is a systematic approach that HHAs can implement and follow in order to continuously improve the quality of care they provide. Under OBQI, quality is measured against the ultimate yardstick - patient outcomes. OBQI is fundamentally a two-stage process that requires the collection of OASIS data for all patients in the agency, except those exempted by regulation.

The first stage of OBQI is outcome analysis based on the OASIS data. The analysis is based on an agency-level report showing the agency's present performance regarding patient outcomes relative to a national measure of HHA patients. Outcome reports are generated at the SA and retrieved by the HHA through the same communication process

the HHA uses to transmit OASIS data. Subsequent outcome reports contain comparisons of an agency's present patient outcomes performance relative to the preceding time period for the agency and relative to a national measure of HHA patients. From these reports, HHAs can target areas for improvement as part of their overall quality assurance process.

The second stage of OBQI is outcome enhancement, whereby the agency, using the data from its outcome analysis, identifies opportunities to improve care and develops plans. HHAs are provided with reports on a series of outcomes for their patients in the current year that compares its performance to the prior year and to the national reference (i.e., benchmarking) values.

2202.5A - Using Outcome Based Quality Monitoring (OBQM) and Risk Adjusted OBQI Reports in the Survey Process

(Rev. 1, 05-21-04)

The OBQM reports consist of the case-mix and adverse event outcome reports, which are derived from the OASIS data that HHAs submit to the State. The OBQM reports are available to both the HHA providers and SAs. The case-mix and adverse event outcome reports can be used by HHAs for quality monitoring and improvement purposes. The risk-adjusted OBQI reports provide measures of patient care based on all of the OASIS data items. These reports allow an HHA to proceed to outcome enhancement. It is the outcome enhancement activities that allow an HHA to focus its quality (or performance) improvement activities on select target outcomes, to investigate the care processes that contributed to these outcomes, and to make agency-specific changes in clinical actions that will lead to improved patient outcomes. Using these reports is a first step toward full implementation of the OBQI program. As a part of the pre-survey preparation, surveyors should access and review the OBQM and OBQI reports before surveying an HHA. These reports contain valuable information that may assist surveyors in identifying areas to review during the survey and possibly identify individuals or types of patients to include in the sample selection when on site following guidance provided in the Home Health Survey Protocol Enhancements, effective May 1, 2003 published February 13, 2003 as S&C Memorandum 03-13. The OBQM Manual, (titled "Quality Monitoring Using Case-Mix and Adverse Event Outcome Report" available on the OASIS Web site), provides examples of possible surveyor actions related to adverse event outcomes. The OBQI Manual (titled Outcome-Based Quality Improvement Implementation Manual provides guidance to HHAs for establishing a quality improvement program using the risk-adjusted OBQI reports. This manual is also available on the OASIS Web site.

1. Case-Mix Report

The case-mix report presents a picture, or snapshot, of an HHA's patients at the beginning of a care episode for the time period selected for the report. The beginning of a care episode is marked by either a SOC assessment or a ROC assessment. The body of the case-mix report describes the characteristics of an HHA's Medicare and

Medicaid patients receiving skilled services compared to the rest of the Medicare and Medicaid patients receiving skilled home health services across the country during the same time period. Surveyors should review the case-mix outcome report as described in the OBQM Manual and the Appendix titled "Guidelines for Reviewing Case-Mix and Adverse Event Outcome Reports." Any significant results should be identified after reviewing the report, and highlights noted. This will allow surveyors to begin to identify potential clinical groups of patients that can be included in the case-mix stratified sample for record review and home visits, as part of the onsite survey.

2. Adverse Event Outcome Report

The adverse event outcome report displays incidence rates for untoward events (or outcomes) comparing one HHA's patients to patients in the CMS OASIS National repository for the same time period. Optionally (after the first report), it also may compare an agency to itself at an earlier point in time. Adverse events serve as markers for potential problems in care because of their negative nature and relatively low frequency. Surveyors do not look at the adverse event outcome report in a vacuum. They review this report in light of the actual circumstances surrounding the delivery of care to the specific patients.

As a part of the CoPs, HHAs are required to conduct an annual evaluation of their total program, including patient services. HHAs are also required to conduct quarterly clinical record reviews to evaluate the care provided under the HHA's policies. The CoPs require an agency to have policies and procedures to promote patient care that are appropriate, adequate, effective and efficient. HHAs have had access to the OBQM reports since January 26, 2001, and should be incorporating a review and investigation of these reports into their evaluation and patient care review programs and including them as part of their quarterly record review.

3. Risk Adjusted OBQI Reports

The risk adjusted OBQI reports are the third and final of the OASIS-based reports. These agency-level reports allow individual HHAs to assess their own performance with respect to patient outcomes and compare their performance to a national reference or benchmark. In addition, HHAs can use the OBQI data to target and develop plans of action to improve or maintain HHA performance and patient outcomes. The risk adjusted OBQI reports became available to all HHAs in February 2002.

Until a regulation is published requiring HHA use of OBQM and OBQI reports, CMS does not require HHAs to use the OBQI reports. CMS expects that HHAs will choose to use the OBQI reports for quality improvement and for consumer education. In CMS-sponsored demonstrations where the OBQI process has been tested, many HHAs have demonstrated significant improvements in targeted patient outcomes, such as decreased hospitalization rates. The OBQI reports represent, for the first

time, a system of benchmarking that is case-mix adjusted for each HHA. This means that every HHA can be compared to national reference values regardless of the types of patients it serves compared to another HHA. Therefore, an HHA that strives to provide quality care services to its patients will be able to determine its performance and to identify areas for improvement or reinforcement with the risk-adjusted OBQI report.

2202.5B - Case-Mix Stratified Sample

(Rev. 1, 05-21-04)

Surveyors will continue to select a case-mix stratified sample for record reviews and home visits since this requirement is explicitly referenced in §1891 of the Act. For example, surveyors will continue to routinely assess the ability of the HHA to provide quality care by conducting the following activities:

- Evaluating the current status of the patient as reflected in the comprehensive assessment, plan of care and visit notes;
- Verifying that all drugs and treatments are provided according to a physician's order and that the HHA has reviewed all drugs for potential adverse effects and drug reactions;
- Reviewing the plan of care to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs;
- Reviewing the timeliness of services provided to the patient;
- Evaluating the HHA's ability to coordinate care and services;
- Reviewing the patient's progress toward the achievement of desired outcomes;
- Verifying that any changes in the patient's medical condition were reported to the physician and recorded, including documentation of verbal orders with written confirmation; and
- Evaluating the appropriateness of patient's continuation of services or discharge at the time of record review.

However, the scope of patients eligible for the case-mix stratified sample may include both current and discharged patients. Surveyors may also identify clinical areas and select patients for review on site as part of their off-site survey preparation. The outcome reports may point to concerns that surveyors need to address during the survey and surveyors will now be able to include in the sample patients representing the identified concerns.

The surveyor should continue to use the HHA's current visit schedule (or plans for visits) during the week that the surveyor(s) is on site to develop the sample for clinical record review with home visits. The sample for clinical record review without home visits may include records of patients that have been discharged by the HHA.

2202.5C - Privacy Act Requirements

(Rev. 1, 05-21-04)

1. SA/RO Use of OASIS Data

Each SA or RO user authorized to access and use the OASIS data or reports derived from OASIS data must comply with the provisions governing the privacy and security of this Federal information system. Each user with authorized access to the system, records, and reports must agree to maintain appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the patient identifiable data and to prevent unauthorized access to the data. Each user is required to have an individual valid User ID and a secure password. Each user is obligated to protect the confidentiality of the OASIS data. As noted in the June 18, 1999, and December 27, 2001, "Federal Register" notices of the OASIS system of records: "No user shall disclose, release, reveal, show, sell, rent, lease, loan or otherwise grant access to the data to any person." The Federal Privacy Act of 1974 provides criminal penalties and fines for certain violations.

2. HHA Use of OASIS Data

The HHAs are required, as a part of the CoPs to maintain the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data and reports, and may not release patient identifiable OASIS information to the public. Therefore, neither the State nor the HHA may release any of the OBQM or OBQI reports or the information contained in them.

2202.5D - Accessing OBQM and OBQI Reports

(Rev. 1, 05-21-04)

The authorized SA and RO user needing access to these reports must have a valid user identification and a secure password. These are obtained by submitting a request to the CMS Central Office via the State system coordinator through the CMS RO. Approved requests will be assigned the required user identification and password. SAs and ROs will access the OBQI and OBQM reports from the Certification and Survey Provider Enhanced Reports (CASPER) link located under the CASPER title on the QIES to Success Web site. The CASPER Home page will display, requiring entry of the login ID and password necessary to access the reporting tool. For most SA and RO users, this login ID and password are the same that are currently used when accessing the OBQM

Reports. HHAs access their OBQI and OBQM reports in the same way they access their OASIS validation reports, by connecting to the OASIS State System via the MDCN and selecting the applicable menu option.

2202.5E - Role of the OASIS Coordinators in OBQI

(Rev. 1, 05-21-04)

The OASIS coordinators work directly with the HHAs to help them access and review the OBQM, risk-adjusted OBQI, and Data Management System reports. In addition, the OASIS Coordinators support and train State surveyors to access, review, and interpret the reports as needed. States do not advise HHAs on which outcomes to target nor do they provide advice on care practices.

2202.6 - OASIS Instructions

(Rev. 1, 05-21-04)

2202.6A - OASIS User's Manual

(Rev. 1, 05-21-04)

The OASIS User's Manual is intended for use by HHAs in implementing the regulations for comprehensive patient assessments, including data collection and reporting using the OASIS. In hard copy form, it consists of three separate manuals in a single volume. The manuals are also available for download (as individual components) from the OASIS Web site. In addition, each State receives a copy on CD. Hard copies of the OASIS User's Manual, as well as other OASIS documents, are available from the National Technical Information Service by calling: 1-800-553-6847. The electronic version of the manual (both downloadable and CD) is indexed to facilitate topical and/or text searches. The components include the following.

1. OASIS Implementation Manual: Implementing OASIS at an HHA to Improve Patient Outcomes

   This manual was prepared by the Center for Health Services Research, Denver, Colorado. It covers the overall OASIS implementation process from a clinical and management perspective and includes detailed information needed to train HHA clinical staff to use OASIS as part of the comprehensive assessment and materials to assist operationally in the implementation of OASIS data collection and data reporting. Many of the questions HHAs ask specific to the types and uses of OASIS data sets and OASIS data items are answered in the OASIS User's Manual. Specifically, in Chapter 8 - OASIS in Detail, each data item is identified and defined. Information that includes the time point the item is to be collected by the HHA and instruction for responses and assessment strategies is also present.

2. OASIS National Automation Project: HHA System User's Guide

   This manual was prepared by the Iowa Foundation for Medical Care (IFMC), West Des Moines, Iowa. It covers the data submission process for HHAs, including how they are to access the OASIS State System, procedures for electronically submitting data (including corrections of previously submitted data), and interpretation of feedback reports from the OASIS State System.

3. OASIS HAVEN System Reference Manual

   This manual was prepared by Fu Associates, Arlington, Virginia. It covers the use of HAVEN software, which was developed to provide HHAs with software for data entry, editing, and validation of OASIS data. It includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions. This manual, in electronic form, is also included with the HAVEN software.

As updates are made to the OASIS User's Manual, each State is provided with one set of hard copy change pages. In addition, all updates to the manual are posted on the OASIS Web site.

2202.6B - Other Manuals

(Rev. 1, 05-21-04)

For SAs only, there is a detailed User's Manual for SA System Administrators who, pursuant to the regulations, are required to administer and maintain the OASIS system at the State level. This manual includes an overview of the components of the OASIS State System and provides the instructions necessary to administer and maintain them.

2202.6C - Other Teaching Tools

(Rev. 1, 05-21-04)

In addition to the OASIS User's Manual for HHAs, there are other sources of information available to help States implement OASIS. They are:

1. The OASIS Trainer's Manual

   This manual was distributed together with the OASIS User's Manual at OASIS trainings held October 1998. This manual was developed to assist State OASIS educational coordinators and related State staff in the planning and implementation of OASIS training programs for HHAs in their States. The Trainer's Manual is not available on the OASIS Web site.

2. A Computer-Based Training (CBT) CD Demonstrating the OASIS Data Submission Process

   One copy of this CD was mailed to each SA. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

   - Establishing the Communication Connection;
   - Submitting OASIS Data Files; and
   - Initial Feedback and Validation Reports.

3. A Computer-Based Training CD Demonstrating use of the HAVEN Software

   One copy of this CD was mailed to each SA. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

   - A HAVEN Overview;
   - Maintaining an Agency Database;
   - Maintaining an Employee Database;
   - Maintaining a Patient Database;
   - Assessment Addition;
   - Exporting a File; and
   - Assessment Correction and Deletion.

4. QIES Technical Support Office (QTSO) Web site

   In addition to the above sources of information available to help States implement OASIS, IFMC's QTSO Web site contains current and relative OASIS information, training manuals, HAVEN software, software patches, slides from past OASIS conferences and video files that can be viewed on line at http://www.qtso.com/

5. OASIS Web site (http://www.cms.hhs.gov/oasis/)

   The CMS OASIS Web site was made available in July 1998 to store and disseminate policy and technical information related to OASIS for use by the home health community. The information posted on the OASIS Web site is intended to assist HHAs, SAs, software vendors, professional associations, and other Federal agencies in implementing and maintaining OASIS as efficiently as possible. CMS continually updates and modifies the OASIS Web site in an effort to provide HHAs and other principals with information necessary to understand and implement OASIS.

6. OASIS Web-based Training Internet site

The OASIS Web-based Training (WBT) Internet site was made available in October 2003 as a comprehensive training tool designed to provide home health agency clinicians and state agency surveyors with detailed instructions on each OASIS item. The WBT covers the following topics:

- Why OASIS?
- OASIS and the Comprehensive Assessment;
- How to effectively conduct a comprehensive assessment; and
- OASIS Conventions, as well as providing detailed instruction and quizzes on each OASIS item.

Each of the lessons contains an introduction, the rationale of why the topic is important, the lesson objective, assessment strategies for items or groups of items within the lesson, special notes or alerts on the respective OASIS items, and a wrap-up.

CMS is providing this new training tool to individual clinicians and home health agencies nation-wide at no cost. This interactive and interesting Internet site is available at: http://www.oasistraining.org/.

CMS expects this training will allow independent access for individual clinicians and others to understand the OASIS items and the most effective assessment leading to greater accuracy and consistency in selecting responses. We hope that the positive clinician behavior demonstrated in the videos will motivate clinicians to learn how to effectively perform a comprehensive assessment without fatigue to the patient or the clinician.

This Internet site offers many benefits to the home health agency. This site could be useful for orienting clinicians new to home care, as a resource to clarify a specific OASIS item for seasoned clinicians, it facilitates competency testing, and develops staff who are effective and efficient in conducting assessments. For individual clinicians this is a site

that offers opportunities to expand assessment approaches and strategies in self-study continuing education, free of charge, while it presents essential content to increase accuracy and provided clinical decision-making skill through principle-based presentation. The site offers additional resources for investigation, and is accessible from any modern computer with Internet access from work or home. We hope this site will promote peer interaction regarding the patient situations, while facilitating group communication about clinical skills, care, and assessment and intervention strategies.

7. OASIS Help Lines

In addition to the OASIS Web site, QTSO Web site, OASIS User's Manual, OASIS Training Manual and CBT modules available through each SA, HHAs can access help through telephone and e-mail hot lines:

- The telephone hotline for assistance with HAVEN and OASIS data submission is: 1-877-201-4721. This is a toll-free number available from 7a.m. - 7 p.m. Central Time. After hours, a voice-mail box is available to record inquiries.

- The e-mail address for assistance with HAVEN and OASIS data submission is HAVEN_help@IFMC.org.

SA and RO OASIS staff have different telephone, FAX, and e-mail hot lines in place for assistance with their clinical questions concerning HAVEN and OASIS data submission. These hot lines are designed for use by SA and RO staff only. SA personnel should contact their State OASIS Coordinator, RO OASIS Coordinator, or central office OASIS staff for this information.

2202.7 - OASIS and the Home Health Prospective Payment System (PPS)

(Rev. 1, 05-21-04)

The home health PPS has been in effect since October 1, 2000, to help ensure appropriate reimbursements for quality, efficient home health care. Additional information on the home health PPS can be found in the Medicare Home Health Agency Manual, sections 201 through 201.14. This and other PPS information is available on the CMS Web site at http://www.cms.hhs.gov/providers/hhapps/default.asp. The following are highlights of the home health PPS system:

- Medicare pays HHAs for each covered 60-day episode of care. As long as beneficiaries continue to remain eligible for home health services and episodes are not overlapping and are medically necessary, they may receive an unlimited number of episodes of care. Payments cover skilled nursing, home health aide visits, covered therapy, medical social services and routine and non-routine medical supplies.

- A case mix methodology adjusts payment rates based on characteristics of the patient and his/her corresponding resource needs (e.g., diagnosis, clinical factors, functional factors, and service needs). The 60-day episode rates are adjusted by case mix methodology based on data elements from the OASIS. The data elements of the case mix adjustment methodology are organized into three dimensions that capture clinical severity factors, functional severity factors, and service utilization factors influencing case mix.

- To ensure adequate cash flow to HHAs, the home health PPS has set forth a split percentage payment approach to the 60-day episode. The split percentage occurs through the request for anticipated payment (RAP) at the start of the episode and the final claim at the end of the episode. For the initial episode, there will be a 60/40-split percentage payment. An initial percentage payment of 60 percent of the episode will be paid at the beginning of the episode and a final percentage payment of 40 percent will be paid at the end of the episode, unless there is an applicable adjustment. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes will be paid at a 50/50 percentage payment split.

- Payment rates will be adjusted to reflect significant changes in a patient's condition during each Medicare-covered episode of care. Payment adjustment will occur due to an unanticipated, significant change in condition (SCIC). In order to receive a new case mix assignment due to a SCIC, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both before and after the patient experienced a SCIC during the 60-day episode.

- An episode with four or fewer visits is paid as a "Low Utilization Payment Adjustment," (LUPA), which is the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage adjusted per visit amount for each of the visits rendered instead of the full episode amount.

Exceptions to OASIS Collection and Reporting Procedures Under PPS

There are some exceptions to the general OASIS collection and reporting procedures that are unique to Medicare PPS patients. There is information on the OASIS Web site that is provided to help HHAs integrate the home health PPS into their existing OASIS data collection procedures. A summary of that information with regard to OASIS data collection and the appropriate M0100 (Reason for Assessment) and M0825 (Therapy Need) response selection is provided below.

A - PPS Start-up

For new patients after October 1, 2000, all applicable (skilled care) patients (not just Medicare patients) accepted for care on or after October 1, 2000, are assessed according to the established time points at 42 CFR 484.

EXAMPLE: A patient whose SOC date is October 15 would be re-assessed for the need to continue services for another certification period during the last 5 days of the current 60-day certification period. In this example, the follow-up assessment would be conducted during the period 12/9/00 through 12/13/00.

B. First 60-day Episode

SOC: M0100 = RFA 1 and M0825 = 0-No or 1-Yes.

C. New 60-day Episode Resulting From Discharge With All Goals Met and Return to Same HHA During the 60-Day Episode. (PEP Adjustment)

SOC: M0100 = RFA 1 and M0825 = 0-No or 1-Yes.

D. New 60-Day Episode Resulting From Transfer to HHA With No Common Ownership (PEP Adjustment to Original HHA)

PEP Adjustment does not apply if patient transfers to HHA with common ownership during a 60-day episode. Receiving HHA completes OASIS, as applicable, on behalf of transferring HHA. Transferring HHA serves as the billing agent for the receiving HHA. Transferring HHA may continue to serve as the billing agent for receiving HHA or conduct a discharge assessment at end of episode. Receiving HHA starts new episode with SOC (if original HHA discharges at end of episode): M0100 = RFA 1 and M0825 = 0-No or 1-Yes.

E. SCIC With Intervening Hospital Stay During (But Not at the End of) Current Episode

ROC: M0100 = RFA 3 and M0825 = 0-No or 1-Yes (or NA if no SCIC).

- If patient was transferred to the hospital and returns during the current episode, HHA completes the ROC assessment (RFA 3) within 48 hours of the patient's return, as required**.** The ROC assessment (RFA 3) also serves to determine the appropriate new case mix assignment for the SCIC adjustment.

- It is recommended that for Medicare PPS patients, HHAs complete transfer without discharge assessment at the time of transfer, in case the patient returns to the HHA within the current 60-day period.

F. SCIC With Intervening Hospital Stay and Return Home During the Last 5 Days of an Episode (Days 56-60)

HHA completes ROC: M0100 = RFA 3 and M0825 = 0-No or 1-Yes and Follow-Up (M0100) = RFA 4 and M0825 = 0-No or 1-Yes.

NOTE: The requirement to complete two assessments in this situation is unique to PPS patients. With all other pay sources, only the ROC is necessary if the two time periods overlap.

- If patient was transferred to the hospital and returns home during the last 5 days of the current episode (days 56-60), HHA completes the ROC assessment (RFA 3) within 48 hours of the patient's return, as required. M0825 = 0-No or 1-Yes, based on therapy need for the current certification period.

- The Follow-Up assessment (RFA 4) is required during the last 5 days of the certification period. For payment purposes, this assessment serves to determine the case mix assignment for the subsequent 60-day period. A new Plan of Care is required for the subsequent 60-day episode.

- The Follow-Up assessment (RFA 4) is required in addition to the ROC assessment (RFA 3) if claiming a SCIC adjustment for the last few days of the current episode because the adjusted portion of the current episode and the new 60-day episode are subject to separate payment categories, i.e., home health resource groups (HHRGs).

- If no change in case-mix or HHA chooses not to claim a SCIC adjustment, only a ROC assessment is needed, as above. Remember that M0825 will be used to predict therapy need for the next 60 days and should be completed with this in mind.

G. SCIC Without Intervening Hospital Stay

Other Follow-Up Assessment: M0100 = RFA 5 and M0825 = 0-No or 1-Yes.

H. Subsequent 60-Day Episode Due to the Need for Continuous Home Health Care After an Initial 60-Day Episode

Recertification (Follow-up): (M0100) = RFA 4 and (M0825) select 0-No or 1-Yes.

I. Patient's Inpatient Stay Extends Beyond the End of the Current Certification Period. (Patient Returns to Agency After Day 60 of the Previous Certification Period)

SOC: M0100 = RFA 1 and M0825 = 0-No or 1-Yes. When patient returns home, new orders and plan of care are necessary.

- At time of transfer to inpatient facility, HHA completes transfer. If transferred without discharging, starts new episode and completes a new SOC assessment when patient returns home.

NOTE: M0825 = NA is applicable for non-Medicare patients and Medicare patients where a SCIC adjustment is not indicated (for example, patient returns to home care from the hospital within the current episode and ROC indicates no change in current case mix.)

2202.8 - Surveying for the OASIS Requirements

(Rev. 1, 05-21-04)

The comprehensive assessment regulation requires that HHAs use a standard core data set, i.e., OASIS, when evaluating adult, non-maternity Medicare and Medicaid patients (except those receiving exclusively homemaker or chore services.) The OASIS meets the condition specified in §1891(d) of the Act, which requires the Secretary to designate an assessment instrument in order to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of the patient as reflected in the plan of care. These regulatory changes are an integral part of CMS' efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Since the requirement to report OASIS data to the OASIS State System is not part of the standard survey process, while determining compliance with the comprehensive assessment of patients is, both offsite and onsite monitoring are required to determine compliance with the OASIS CoPs. The State OASIS Educational and Automation Coordinators can assist with the offsite monitoring for OASIS compliance and in providing available OASIS reports, (e.g., data management, quality monitoring and quality improvement reports) to surveyors. HHAs that do not collect and report accurate and complete OASIS data for all applicable HHA patients risk citations at the standard and condition levels. HHAs found not to be in compliance may be subject to enforcement actions and/or termination from the Medicare program.

2202.8A - Condition of Participation: Comprehensive Assessment of Patients

(Rev. 1, 05-21-04)

This CoP states that a comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan. HHAs complete the OASIS items as part of the clinician's total assessment process. This process is not based solely on interviewing the patient. Conducting a patient's comprehensive assessment involves both observation and interview. These data collection techniques complement each other. Many HHA

clinicians begin the assessment process with an interview by sequencing questions to build rapport and trust. Others choose to begin the assessment process with a familiar procedure such as taking vital signs in order to demonstrate clinical competence to the patient before proceeding to the interview. HHAs are expected to complete all OASIS items as accurately as possible while minimizing burden and intrusion on the patient.

HHAs should not force patients to cooperate with the assessment process; rather, they must do the best they can to assess patients who do not fully cooperate with the assessment process. Since collecting OASIS information rarely depends solely on patient interview, HHAs are expected to complete, encode, and transmit all OASIS data items. If patients refuse to answer some questions that are part of the OASIS assessment, HHAs may still deliver care to the patient as long as they complete and submit the OASIS assessment to the best of their ability.

States may advise HHAs that seem to report difficulty with specific OASIS items to review the processes of performing a comprehensive assessment with their staff. Sometimes such difficulties indicate that staff might benefit from additional training or retraining in assessment skills. The OASIS Web-based Training Internet site provides additional guidance on "OASIS and the Comprehensive Assessment" and "How to effectively conduct a comprehensive assessment" for clinicians who are challenged by these activities.

- As stated in the CoPs, each patient (except those under 18; receiving maternity services; receiving only services such as homemaker or chore services; or, until sometime in the future, receive personal care services only), regardless of payor source, is expected to receive from the HHA a comprehensive assessment that accurately reflects the patient's current health status and incorporates the exact language of the OASIS data items required for the time points specified in this condition.

- The requirement to collect OASIS data as part of the comprehensive assessment for non-Medicare /non-Medicaid patients is temporarily suspended, effective December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

The CoP is comprised of the following five standards.

1. Initial Assessment Visit

   This standard requires that an initial visit be performed to determine the immediate care and support needs of the patient. The initial assessment visit requirement is intended to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion. It is not required that a SOC comprehensive assessment be completed at this visit, although the HHA may choose to do so. If the HHA does not complete the SOC comprehensive assessment during the initial visit, then the comprehensive assessment must be completed and updated according to the required time points.

   - The initial assessment visit is conducted by a registered nurse and must occur either within 48 hours of referral, or within 48 hours of the patient's return home from a hospital stay of 24 hours or more for any reason other than diagnostic testing, or on the SOC date ordered by the physician.

   - For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients.

   - When rehabilitation therapy (speech-language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation professional. For the purpose of the initial visit, a therapy case that includes knowledge of skilled nursing for a one-time visit to remove sutures or draw blood is not considered a therapy-only case. The initial visit must be conducted by the qualified registered nurse.

NOTE: While Medicare pays for occupational therapy, eligibility for the Medicare home health benefit cannot be established based solely on the need for that service. The need for occupational therapy does not establish eligibility for the Medicare home health benefit. However, the Medicare home health patient with multiple service needs can retain eligibility if, over time, the only remaining need is for occupational therapy. Therefore, under the Medicare benefit, the OT cannot conduct the initial assessment. An

OT can conduct the Follow-Up assessment and those associated with transfers and discharges. Occupational therapy, could, however, establish eligibility, in some States, under the Medicaid program. In the case of Medicaid patients (or Medicare patients receiving therapy services), if the need for a single therapy service either establishes eligibility or allows eligibility to continue once it is otherwise established, the corresponding practitioner, (including a PT, SLP, or OT) can conduct any of the designated assessments.

2. Completion of the Comprehensive Assessment

   When a patient is first admitted to the HHA, a comprehensive assessment, must be completed no later than 5 calendar days after the SOC date. The comprehensive assessment for all Medicare and Medicaid patients receiving skilled services must include OASIS data. OASIS data is not required for non-Medicare/non-Medicaid patients at this time. However, HHAs may include OASIS data if they choose. Additional comprehensive assessments are required throughout a patient's course of treatment.

   - A registered nurse must complete the comprehensive assessment and, for Medicare patients, confirm eligibility for the Medicare home health benefit.

   - When physical therapy or speech-language pathology is the only service ordered by the physician, the PT or SLP may complete the comprehensive assessment. For the purpose of the SOC comprehensive assessment, a therapy case that includes skilled nursing for a one-time visit to remove sutures is not considered a therapy-only case. The SOC assessment in this case should be conducted by the qualified registered nurse but may be completed by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The HHA can decide how best to approach the assessment process at the required time points. For other than Medicare, OTs may complete the SOC assessment when the need for occupational therapy establishes program eligibility. (See **NOTE** above concerning eligibility for the home health benefit and occupational therapy services.)

   - The SOC comprehensive assessment may be completed in more than one visit as long as it is completed within the 5-day time frame required by the regulations.

   - Non-clinical staff, i.e., those not qualified by current regulation, may not assess patients or complete assessment items; however, non-clinical staff or data entry operators may enter the OASIS data collected by the qualified skilled professional into the computer. Many elements in the Clinical Records Items section (which identifies the patient) of each OASIS data set may be completed initially by clerical staff as part of the

intake/referral process; but should be verified by the qualified clinician doing the assessment.

Master of Social Work Only Evaluations

Visits for medical social work assistance only are frequently requested by case managers. A visit for medical social work in order to evaluate the patient's need or eligibility for community services generally is not considered a visit to conduct a comprehensive assessment of the patient. If a physical assessment of the patient is conducted, as is required by the comprehensive assessment regulations, it must be done by a qualified person. In this case, that qualified person must be an RN, PT, SLP or OT (as applicable).

Drug Regimen Review

The drug regimen review requirement was moved from the previous plan of care requirements to the new comprehensive assessment requirement to reflect the true nature and purpose of this activity. The comprehensive assessment must include a review of all medications the patient is currently using in order to determine compliance with drug therapy, significant side effects and drug interactions, potential adverse effects and drug interactions, ineffective drug therapy, and duplicate drug therapy.

The previous requirements for drug regimen review were modified by eliminating the actual identification of "adverse actions" and "contraindicated medications" and substituting the requirement to review drug therapy compliance, drug interactions, and duplicative drug therapy.

3. Update of the Comprehensive Assessment

In order to have data that is comparable across HHAs, OASIS data must be collected at uniformly defined time points including recertification. This requirement is not expected to add to the number of skilled visits provided by the HHA. Many HHAs arrange visit schedules to accommodate home health aide supervisory requirements and patient and care giver schedules. HHAs are expected to similarly adjust the patient's visit schedule in order to accommodate OASIS time points. OASIS reassessment visits that are not part of a treatment visit are overhead/administrative costs and not separately billable visits. They do not require a physician order.

The comprehensive assessment, which includes the OASIS data items for Medicare and Medicaid patients, should be updated and revised no less frequently than:

- During the last 5 calendar days of the current 60-day certification period beginning with the SOC date (Follow-up OASIS data set);

- Within 48 hours of (or knowledge of) transfer to an inpatient facility (Transfer to an Inpatient Facility OASIS data set, with or without agency discharge);

- Within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (ROC OASIS data set);

- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay other than a hospital; and (See major decline or improvement in the patient's health at 4. below.)

- Within 48 hours of (or knowledge of) discharge to the community or death at home (Discharge OASIS data set).

- For non-Medicare/non-Medicaid patients, HHAs must provide each agency patient with a patient-specific comprehensive assessment at the above time points to accurately reflect the patient's current health status and the patient's progress toward achievement of desired outcomes.

In a case involving more than one discipline, the SOC assessment should be conducted by the qualified registered nurse but may be conducted by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The comprehensive assessment updates should include the appropriate OASIS items as indicated on the data set for the respective time points, (i.e., SOC, ROC, Follow-Up, transfer to inpatient facility with or without discharge, discharge, and death at home).

If home health care is resumed after an inpatient stay, the comprehensive assessment must include the OASIS items appropriate for assessment after an inpatient stay. If the patient is not formally discharged at the time of transfer to an inpatient facility, the agency completes a comprehensive assessment that includes the ROC OASIS data items.

If the patient is formally discharged from the HHA, the data collection proceeds on the basis of a new agency SOC date that follows the inpatient stay; therefore, a SOC comprehensive assessment is conducted. The ROC and SOC (minus the Patient Tracking Sheet) OASIS data sets are actually the same data set. For purposes of OASIS data collection, the HHA can establish its own internal policies regarding criteria for formal discharge versus interrupting home care services but maintaining the patient on the HHA admission roster, i.e., placing the patient on

"hold" status. (See OASIS and the Home Health Prospective Payment System for exceptions to this general rule.)

If the patient is under the care of the HHA and is not formally discharged prior to the end of the current 60-day period, the HHA conducts the next comprehensive assessment during the last 5 days of the current 60-day period beginning with the original SOC date. For example, if the SOC date were June 25, 2004, the patient would be reassessed between August 18 and August 22, 2004.

If the HHA transfers a patient to an inpatient facility and places the patient on "hold" status, no further assessments are conducted and no data is collected while the patient is in the inpatient facility. The HHA is not providing care while the patient is on "hold" during the inpatient stay. At the time the patient is transferred to the inpatient facility, a transfer assessment (response 6 selected for M0100) is completed. When the patient returns to home care, the HHA completes the ROC assessment (response 3 selected for M0100). (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

The ROC assessment is required within 48 hours of the patient's return home from the inpatient facility unless otherwise determined by physician's orders. The Follow-up assessment is required during the last 5 days of the current 60-day (recertification) period. It is possible for these two time periods to overlap. If they do, M0100, ROC (response 3), should be marked. If these two periods DO NOT overlap, two comprehensive assessments should be completed in accordance with the regulations. One assessment is done for the ROC while the other is done for the follow-up time point. (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

4. Major Decline or Improvement in the Patient's Health Status

The OASIS regulations require that assessments with OASIS data collection be performed at certain time points. In the event an HHA determines that a patient's condition has improved or deteriorated significantly at a point in the episode of care that is not already captured at a required time point, the HHA should collect and report additional assessment information. Each HHA should define major declines or improvements in the patient's health status. Thus, the term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data to:

- Assess a patient on return from an inpatient facility other than a hospital, if the patient was not discharged upon transfer (ROC OASIS data set); and

- As defined by the HHA (Other Follow-up OASIS data set).

NOTE: The ROC and Other Follow-up OASIS data sets are used to determine a SCIC payment adjustment for PPS patients, as applicable. The HHA own

comprehensive assessment can be used without OASIS data for assessing a major decline or improvement in the patient's health status.

5. Incorporation of OASIS Data Items

Integrating the OASIS items into the HHA's own assessment system in the order presented on the OASIS data set facilitates data entry of the items into the data collection and reporting software. Agencies may integrate the items in such a way that best suits their assessment system. Some agencies may wish to electronically collect their OASIS data and upload it for transmission to the State. As long as the HHA can format an output file for transmission to the State (that is, in the 1448-byte data string format specified by CMS), it doesn't matter in what order it is collected; however, this is not recommended because of the skip patterns built into the OASIS data set. In accordance with the regulations, data MUST be transmitted in the sequence presented on the OASIS data set. The HAVEN software will prompt HHAs to enter data in a format that will correctly sequence it and ultimately be acceptable for transmission.

HHAs collecting data in hard copy or electronic form must incorporate the OASIS data items into their own assessment instrument using the exact language of the items. Agencies are expected to replace similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the end. For agencies using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, software that capitalizes these words is acceptable. Including the M00 numbers when integrating is also recommended. In this way, the HHA will know that the M00 labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to uncompleted OASIS data items.

HHAs may wish to incorporate the assessment categories (e.g., ADLs/IADLs, Medications, etc.) into their own assessment instrument in a different order than presented on the OASIS data set; however, as stated above, the agency must consider any skip instructions contained within the questions in the assessment categories and provide the proper instructions.

2202.8B - Record Keeping

(Rev. 1, 05-21-04)

Since the OASIS data set is incorporated into the HHA's comprehensive assessment, the clinical record must be maintained according to existing CoPs for clinical records. Records of both active and discharged patients must be readily retrievable for use by SA staff. Although not required, it is recommended that HHA should print hard copies of the electronic validation records received from the SA and store the validation records in an electronic format for twelve months, until the next set of OBQI reports are available.

2202.8C - Condition of Participation: Reporting OASIS Information

(Rev. 1, 05-21-04)

Except as specified in the June 18, 1999, notice, HHAs must report OASIS data on all patients (except those under 18, those receiving maternity services, and those receiving housekeeping or chore services only) in a format that meets CMS specifications. HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the SA using the HAVEN software CMS provides or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Once reported to a CMS central database, the compiled, aggregate OASIS data (i.e., outcome reports) can be used by the HHA to determine how it is performing in terms of patient outcomes compared with other HHAs.

1. Encoding OASIS Data

   HHAs must encode (that is, enter OASIS data into a computer using HAVEN or HAVEN-like software) and finalize data entry (lock) for all applicable patients in the agency within 7 days of completing an OASIS data set.

   Once the OASIS data set has been collected at the specified time points described above, HHAs may take up to 7 calendar days after the date of collection to enter and lock the assessment into their computer systems. For example, if the comprehensive assessment is completed on May 2, then, the data must be encoded and locked by May 9. (HHAs should consider implementing a tracking system that considers the 7-day window for correcting OASIS assessments that need corrections before locking.) HHAs will enter their OASIS data into their computers using HAVEN or HAVEN-like software.

   HAVEN will automatically review the data for accuracy and consistency; it will alert the HHA to make any necessary changes in order to finalize or lock the data. The locking mechanism is necessary to ensure the accuracy of the patient assessment at the point in time that the assessment took place. The locking mechanism will prevent the override of current assessment information with future information. HHAs will be prompted by HAVEN to export and store encoded data into an electronic file. The export file is transmitted to the State by the HHA.

2. Accuracy of Encoded OASIS Data

   Encoded OASIS data must accurately reflect the patient's status at the time the information was collected. In preparation for transmission to the State, the HHA should ensure that data encoded into the computer is identical to the OASIS data items completed by the skilled professional. HHAs should, therefore, develop systems to ensure that encoded data matches the OASIS data items completed by the skilled professional. Such a monitoring system could include staff appointed

to audit sample OASIS records after data is encoded as part of the agency's overall quality assurance program.

3. Transmission of OASIS Data

After being exported to a transmission-ready file, the locked data should be transmitted to the State or CMS contractor. HHAs transmit OASIS data at least monthly. By the last day of each month, HHAs should electronically transmit all OASIS data locked during the previous month for each patient (as applicable) to the SA. These monthly transmissions include the SOC comprehensive assessments for patients admitted on or after July 19, 1999, and all other subsequent comprehensive assessments as appropriate for new admissions. These monthly transmissions also include OASIS data collected at the appropriate time points (other than SOC) on patients admitted to the HHA prior to July 19, 1999.

NOTE: CMS requires the encoding and transmission of OASIS information only on patients who are receiving Medicare/Medicaid benefits. This means that for patients with payor source (1) Medicare (traditional fee-for-service), (2) Medicare (HMO/Managed Care), (3) Medicaid (traditional fee-for-service), or (4) Medicaid (HMO/Managed Care) on OASIS item M0150, the HHA must collect, encode and transmit all required OASIS information to the SA. If Medicare/Medicaid is contributing to the payment of the patient's episode of care, the patient is considered a Medicare/Medicaid patient. The payor source for services provided as part of a Medicaid waiver or home and community-based waiver program by a Medicare-approved HHA are coded as (3) Medicaid (traditional fee-for-service) at item M0150.

For non-Medicare/non-Medicaid patients (patients with only pay sources other than M0150 response 1, 2, 3, or 4, the HHA is not required to assess and collect OASIS as part of the comprehensive assessment and agency medical record. Alternatively, the HHA must use its own comprehensive assessment as the requirement to collect OASIS data is temporarily suspended. Non-Medicare/non-Medicaid payer sources include private insurance, private HMO/Managed Care, self pay, programs funded under the Act: for example, Title III, V, XX, or other Government programs.

HHAs must have a computer system that supports transmission of OASIS data via the MDCN to the SA (or other designated location), transmits the export file, and receives validation information. CMS provides HHAs access to the MDCN, a private communications network CMS purchased to ensure the security of OASIS data transmissions to the State. Use of the MDCN allows for all data submitted to the OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the MDCN, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the MDCN and requires no

special action on the part of the HHA other than using browser software that supports industry standard encryption.

HHAs need two different sets of user identification numbers and passwords; one set to access the MDCN and one set to access the OASIS State System. The MDCN is how HHAs transmit their OASIS data. HHAs must install the communications software, which is separate from the HAVEN software, which will allow them to access the MDCN. This software, i.e., the AT&T Global Network Dialer for Windows software is available by download from the AT&T Global Network Web site (http://www.attbusiness.net/softctr/dialer95.html). Instructions for downloading and installing this software are available on the OASIS Web site. Alternatively, HHAs can call the HAVEN help desk at 1-877-201-4721 for help in obtaining and installing this software.

When the OASIS State System receives a transmission file, it validates the reported information while the HHA remains on-line to ensure that some basic elements conform to CMS requirements, such as proper format and HHA information. Once these file checks are complete, a message indicating whether the file has been accepted or rejected is automatically sent back to the HHA's computer via the agency's communication link. If the submission is rejected, an informative message is sent to the HHA.

A file may be rejected for a variety of reasons, for example, the HHA identification name or number may be incorrect or does not match the name or identification number at the State, the number of records indicated in the trailer record does not match the actual number of records submitted, the branch ID may be missing or incomplete, or the incorrect version of the OASIS data specifications is used. The HHA needs to make the corrections and re-submit the file to the State. If the submission passes the initial validation check, the file is checked further for errors or exceptions to the data specifications and a Final Validation Report is generated up to 48 hours later.

4. Data Format

The format used for encoding and transmitting OASIS data should conform with software available from CMS or other software that conforms to the CMS standard layout, edit specifications, and data dictionary including the OASIS data set. Details regarding these specifications are available on the OASIS Web site. The software must also include the most current version of the OASIS data items which will be available on the OASIS Web site at all times. Registered HAVEN users will be mailed a copy of any revised HAVEN software.

HAVEN will prompt the user to enter the data items associated with a required time point by providing the user with the correct screens for the specific type of assessment data required. HHAs will be able to use HAVEN to encode OASIS data, maintain agency and patient-specific OASIS information, and create export

files to submit OASIS data to the OASIS State System. HAVEN provides comprehensive on-line help for encoding, editing, and transmitting these data sets. Additionally, the HAVEN help line (1-877-201-4721) is available to HHAs with questions concerning the installation and use of HAVEN.

The export function in HAVEN allows the user to select Medicare/Medicaid only assessments, non-Medicare/non-Medicaid assessments only, or all assessments. The HAVEN export function produces an ASCII text file from the HAVEN database. This file meets the OASIS data specifications that must be transmitted to the SA. Therefore, the HHA controls assessments to be sent to the SA. The OASIS State System will reject all assessments with a non-Medicare/non-Medicaid payment source, unless they are masked.

The following chart summarizes the required time points and time frames outlines in the regulations for collection, encoding, and reporting OASIS data.

OASIS ASSESSMENT REFERENCE SHEET

RFA = Reason For Assessment

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
01	SOC - further visits planned	Within 5 calendar days following the SOC Date (M0030)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
02*	SOC - no further visits planned	Within 5 calendar days following the SOC Date (M0030)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
04	Recertification - Follow-up	Completed (M0090) every 60 days following SOC: no earlier than day 56 and no later than the day (day 60) on which the certification period ends	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
05	Other Follow-up	Complete assessment (M0090) within 2 calendar days following identification of significant change of patient's condition	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
06	Transferred to inpatient facility - not discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
07	Transferred to inpatient facility - discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
08	Died at home	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
09	Discharged from agency: Not to inpatient facility	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
10*	Discharged from agency: Not to inpatient facility: No visits since SOC assessment	Within 2 calendar days of or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090	No later than the last day of the month following the month the assessment was locked.

*Not required after 12/16/2002

2202.8D - Condition of Participation: Release of Patient Identifiable OASIS Information

(Rev. 1, 05-21-04)

This CoP states that an agent acting on behalf of the agency, in accordance with a written contract, must ensure the confidentiality of all patient identifiable information contained in the clinical record, and may not release it to the public.

The purpose of this provision is to ensure that access to all OASIS data (hard copy as well as electronic data) is secured and controlled by the HHA. This requirement mandates that the HHA ensures the confidentiality of all patient identifiable OASIS information contained in the clinical record and may not release it for any reason other than for what it is intended, which is to transmit to the SA for the development of outcome reports. The HHA's policies should include assignment and maintenance of secure passwords required for encoding and transmitting OASIS data. Policies should narrowly define the qualifications of individuals having access to the OASIS software. For security reasons, passwords are required in the HHA for access to the agency's computer system. A separate password is required for transmitting the OASIS data files to the SA. Privacy and confidentiality of OASIS data are extremely important. Coverage under the Federal Privacy Act of 1974 begins when the data reaches the SA. The Privacy Act protects OASIS data from unauthorized use and disclosure and has been effective in ensuring confidentiality of Medicare data.

HHAs may choose to encode and transmit OASIS data to the SA themselves, or may contract with an outside entity (agent) to fulfill these requirements. Agents acting on behalf of the HHA, such as a data entry and submission vendor or contractor, guided by a written contract, are bound by the same confidentiality rules. The HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements. HHAs using HAVEN are prompted to enter agent information during set up of the HAVEN program.

Data in the hands of an entity contracted by the HHA for data transmission is not covered by the protections of the Privacy Act, therefore policies related to the security of the OASIS data set are required. HHAs contracting with outside entities for data submission are ultimately responsible for the confidentiality and use of that data. Agreements between HHAs and their contractors should specify that the data is only to be used for the purpose in which it is intended, that is, to create outcome reports. As such, identifiable data must be treated in accordance with State law and must not be disclosed without patient consent. Violations of data confidentiality by an entity contracted by the HHA are the responsibility of the HHA and would constitute condition-level non-compliance.

Agents must be aware of the requirements and security policies of the HHA and the SA concerning passwords, as well as the requirements of the OASIS System of Records and the Privacy Act.

2202.9 - Patient Notification of OASIS Collection and Reporting

(Rev. 1, 05-21-04)

Under existing patient rights regulations (42 CFR 484.10(a) and (d), the HHA must provide the patient with a written notice of the patient's rights to confidentiality of medical records in advance of furnishing care to the patient. As part of the patient's rights, the HHA is required to notify the patient of its policies and procedures for disclosure (confidentiality) of clinical records at the time of admission. The HHA must maintain documentation showing that this requirement has been completed; therefore, HHAs must develop admission policies that encourage patient compliance with assessment procedures. Failure to collect and report accurate and complete OASIS data on all applicable patients places the HHA at risk of losing its Medicare certification. States will be able to monitor whether HHAs are submitting the required OASIS information through use of data management reports. While patients have the right to refuse to answer questions posed by the HHA, very few OASIS data items rely solely on direct patient questioning. Therefore, HHAs must complete all OASIS data items as best they can, using their assessment skills.

2202.9A - Informing Patients of OASIS Collection and Reporting

(Rev. 1, 05-21-04)

On or after July 19, 1999, HHAs were required to provide existing patients with privacy notifications. To properly inform patients of their rights under the Privacy Act, the provider must furnish each patient with information required by the Privacy Act. Under the authority of the Privacy Act, notices must contain the following information:

- The right to be informed that OASIS information will be collected and the purpose of collection;
- The right to have the information kept confidential and secure;
- The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Federal Privacy Act;
- The right to refuse to answer questions; and
- The right to see, review, and request changes on their assessment.

The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are available on the OASIS Web site as part of the June 18, 1999, "Federal Register" notice. HHAs must include these statements as part of their admission information. Effective December 8, 2003, HHAs who choose to collect OASIS data on their non-Medicare /non-Medicaid patients must continue to comply with informing patients with privacy notifications.

HHAs that do not collect OASIS data on non-Medicare/non-Medicaid patients are no longer required to provide the Privacy Act notification.

2202.9B - Right to See, Review, and Request Changes

(Rev. 1, 05-21-04)

The "Federal Register" notice of June 18, 1999, requires that, under the Privacy Act, Medicare/Medicaid patients have the right to see, review, and request changes in their assessments. HHAs must accommodate patients (or their representative), who request this review. If the patient disputes OASIS information collected as part of a comprehensive assessment, the HHA has two options; it can agree or disagree with the dispute.

1. The HHA Agrees.--If the HHA agrees with the patient's request, it accepts the request, and changes the applicable OASIS data item(s) on the assessment. A corrected assessment can be submitted to the State, using the terms of the OASIS correction policy.

2. The HHA Disagrees.--If the HHA disagrees with the patient's request, the patient should request written documentation that the disputed information will not be changed by the HHA including the reason(s) why.

If a patient chooses to pursue his/her request at the Federal level, he/she may contact CMS at 1-800-Medicare, toll free, for further review of the disputed issue. The individual contesting a record will be advised to write to the Privacy Officer, CMS, 7500 Security Boulevard, Baltimore, Maryland, 21244-1850, identify the record, and specify the information being contested. This correspondence must include the HHA's written documentation refusing the change. It must also state the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with the Department's regulations (45 CFR 5b.7.) To preserve the privacy of the OASIS/HHA system of records, the Privacy Act Privacy Officer may require that the individual provide the following information for verification purposes: The system name, health insurance claim number, and, for verification purposes, the individual's name (woman's maiden name, if applicable), social security number, address, date of birth, and sex. (Furnishing the social security number is voluntary, but it may make searching for a record easier and prevent delay.) This information must be notarized to preserve the confidentiality of this process.

The HHA Medicare/Medicaid patient who wants to know if there is a record belonging to him/her in the OASIS/HHA system of records, or wants to review the record contained in the CMS OASIS/HHA system of records repository would follow the same process. The patient can contact CMS toll free at 1-800-Medicare to get instructions for how to pursue his/her request.

2202.10 - OASIS and HHAs Seeking Initial Certification

(Rev. 1, 05-21-04)

Prior to receiving Medicare approval, HHAs must meet certain requirements, including enrollment and capitalization, and must provide skilled home health services to a minimum of 10 patients (not necessarily Medicare patients) that is consistent with the Medicare home health CoPs. This includes compliance with the OASIS collection and transmission requirements. New HHAs must demonstrate they can transmit OASIS data prior to the initial certification survey. Specifically, new HHAs must apply for temporary user identification numbers and passwords from the State OASIS automation coordinator in order to electronically transmit to the OASIS State System any encoded and locked SOC or ROC OASIS assessment record(s) for applicable Medicare and Medicaid patients in a test mode. HHA survey staff must communicate with the OASIS coordinators to determine this aspect of compliance prior to the initial onsite survey. SAs and accrediting organizations (AOs) should not schedule initial surveys until the SA or AO has determined the HHA's status with the OASIS transmission requirement. AOs may contact the state directly to determine the status of the new HHA's activities concerning the OASIS transmission process prior to scheduling the onsite survey. The names and phone numbers of the State OASIS contacts are found on the OASIS Web site.

To meet the OASIS transmission requirements prior to the initial certification survey, new HHAs need two different sets of temporary user identification numbers and passwords; one set to access the MDCN and one set to access the OASIS State System.

The OASIS automation coordinator in each SA should assist the new HHA in obtaining the temporary user identification numbers and passwords prior to the initial certification survey. Once the communications software and access are in place, the new HHA must demonstrate that it can transmit OASIS data to the OASIS State System by (1) making a test transmission of any SOC or ROC OASIS data that passes CMS edit checks; and (2) receiving validation reports back from the OASIS State System confirming data transmission. Once Medicare approval has been determined, the State assigns a permanent user identification number and password for the new HHA's access to the OASIS State System. The HHA must apply for permanent user identification numbers and passwords for access to the MDCN by contacting the MDCN help desk at 1-800-905-2069.

Transmissions of test data prior to the official date of approval should be deleted from the OASIS State System by the SA.

2210A - Determining Compliance With the OASIS Transmission Requirements

(Rev. 1, 05-21-04)

Depending on the method of transmission the HHA chooses, the SA needs to determine compliance in one of the following ways:

- If the new HHA chooses to independently transmit OASIS data from its own office, the State HHA survey team and OASIS coordinator must communicate with each other to establish that the new HHA has successfully transmitted test OASIS data using the appropriate temporary user identification numbers and passwords, prior to onsite survey. The HHA should maintain all copies of validation reports for its records.

- If the new HHA chooses to use a software vendor to meet the OASIS encoding and/or transmission requirement on its behalf, the HHA must still establish connectivity to the OASIS State System via the software vendor. The HHA should have a written contract that describes this arrangement. The HHA or its software vendor must apply for the applicable temporary user identification numbers and passwords from the SA in order to establish connectivity with the OASIS State System. As described above, the HHA survey team and OASIS coordinator must communicate with each other to establish that the software vendor, on behalf of the new HHA, has successfully transmitted test OASIS data using the appropriate temporary user identification numbers and passwords, prior to onsite survey. The HHA should obtain copies of all validation reports from its software vendor for its records.

- If the new HHA chooses to use another certified HHA to meet its transmission requirements, for example, another established HHA in the chain or other established but non-related HHA, the HHA must still demonstrate connectivity to the OASIS State System via the other established certified HHA. The new HHA or other HHA must apply for temporary user identification numbers and passwords, unique to the new agency, from the SA, in order to establish connectivity with the OASIS State System. The new HHA must have clearly written policies outlining the procedures in place with the other HHA with regard to OASIS collection, encoding and submission to the OASIS State System and the sharing of feedback reports from the OASIS State System with the new HHA.

2210B - HHAs Seeking Initial Certification Through an Approved Accreditation Organization (AO)

(Rev. 1, 05-21-04)

An HHA may choose to obtain initial Medicare certification by electing the deemed status option through an approved AO that has been granted deeming authority for Medicare requirements for HHAs. There are currently two AOs with deeming authority - the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP). HHAs seeking initial certification through the deemed status option still must apply to the SA for user identification numbers and passwords in order to demonstrate compliance with OASIS submission requirements prior to approval.

When the SA receives a request from an HHA interested in seeking Medicare deemed status through accreditation by JCAHO or CHAP, the State ensures that the HHA understands its obligation to meet the OASIS requirements, even when the AO conducts the initial certification survey. This includes compliance with the OASIS collection and transmission requirements.

If the SA receives a certification packet from an HHA seeking Medicare certification based on its accreditation through a deemed status program, it is the SA's responsibility to determine that the HHA meets its OASIS transmission responsibilities. The OASIS transmission responsibility may be met in one of the three ways described above.

2210C - Exceptions to Demonstrating Compliance With OASIS Submission Requirements Prior to Approval

(Rev. 1, 05-21-04)

New HHAs that intend to admit or treat only patients to whom OASIS currently does not apply, i.e., patients under 18, maternity, and patients receiving only unskilled care or chore services are not expected to demonstrate compliance with OASIS submission requirements prior to approval.

These HHAs must attest this intention to the SA. After certification, if there is a change in the HHA's policies that includes the acceptance of patients to whom OASIS applies, the HHA is expected to install the necessary communications software and contact the SA and MDCN for the applicable user identification numbers and passwords.

2210D - Compliance Dates and PPS

(Rev. 1, 05-21-04)

Compliance with the rest of the CoPs is determined via an onsite survey by the SA and any applicable subsequent actions or revisions required of the HHA following the initial

survey. After survey, the new HHA cannot bill Medicare for payment of services to Medicare beneficiaries until the effective date for Medicare participation has been determined by the CMS RO.

Realistically, notification of the effective date may come many weeks after the initial survey of the HHA. In addition, the date of official compliance may vary depending on the outcome of the onsite survey. As described in §2780, the date of compliance is either:

1. The date the onsite survey is completed if, on the date of the survey the HHA meets all CoPs and any other requirements required by CMS; or

2. If the HHA fails to meet any of the requirements as a result of the onsite survey, compliance is the earlier of:

    - The date the HHA meets all requirements; or

    - The date the HHA meets all the CoPs and submits an acceptable plan of correction for standard level deficiencies.

Payment under Medicare for services provided prior to the effective date for Medicare participation is not permitted. As such, it is important that new HHAs seeking payment under Medicare establish the required 60-day episode on or after the effective date of their Medicare participation.

2210E - Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification

(Rev. 1, 05-21-04)

If the HHA is confident that it has met all CoPs and all other Medicare requirements at the time the initial survey is completed, the HHA is advised to do a new SOC assessment, (RFA 1) on each of its Medicare patients at the first billable visit after the onsite survey. The HHA should delay encoding and transmitting the assessment until the Medicare provider number is assigned.

Once the provider number has been assigned, the HHA can go back and encode the collected OASIS information, obtain the necessary payment system codes for billing under PPS, and transmit the information to the OASIS State System as production (i.e., "live") data. The date of this assessment will become day 1 of the HHA's first 60-day episode under Medicare, as long as the assessment was done in conjunction with a billable visit. Warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If compliance (i.e., the effective date) is not the date of the onsite survey, it will be based on D.2. above, as further outlined in §2780. The HHA should, again, do a new SOC assessment (RFA 1) on each of its Medicare patients at the first billable visit after the

anticipated date of compliance, delay encoding and transmitting the assessment until the Medicare provider number is assigned, and continue as outlined in the paragraph above. That is, the HHA should go back and encode the collected OASIS information, obtain the necessary payment codes for billing under PPS, and transmit the information to the OASIS State System as production data. As above, warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If the new HHA did not conduct a SOC (RFA 1), ROC (RFA 3), or Follow-up (RFA 4) OASIS assessment during the time between the effective date for Medicare participation and the date the HHA learns of its approval, the HHA should conduct a SOC assessment, as soon as possible. This assessment can be used to generate the payment code used for billing under Medicare. The SOC date should reflect a date that is consistent with the first billable visit after the effective date for Medicare participation, as stated above.

2210F - Instructions to New HHAs Concerning all Other Patients

(Rev. 1, 05-21-04)

For all other patients treated by the HHA (i.e., non-Medicare patients), if a new start of care date is not required by the patient's pay source, the HHA should encode and transmit all OASIS assessments as required by current regulation that were collected after the effective date of Medicare participation. These assessments should be submitted in the production mode using the newly assigned provider number. The HHA should continue with the OASIS assessment schedule already established based on the patient's admission date.

2202.11 - Correction Policy

(Rev. 1, 05-21-04)

HHAs have the ability to electronically correct nearly all errors found in their production OASIS submissions. SAs should not be accepting requests for manual key field changes. Instead, HHAs should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 and above will give HHAs the ability to electronically correct nearly any kind of assessment errors.

Key Fields and Non-Key Fields

A description of key fields is below. Non-key fields are all other fields making up the OASIS data set that are not key fields.

KEY FIELDS	
Patient Identifiers:	
M0040_PAT_LNAME	Patient last name
M0040_PAT_FNAME	Patient first name
M0064_SSN	Patient social security number
M0066_PAT_BIRTH_DT	Patient date of birth
M0069_PAT_GENDER	Patient gender
HHA Identifiers:	
HHA_AGENCY_ID	Unique Agency ID code
Assessment Event Identifiers:	
M0100_ASSMT_REASON	Reason for completing assessment
M0090_INFO_COMPLETED_DT	Date assessment information completed (This is a key field only on recertification or follow-up assessments where RFA=04 or 05)
M0030_START_CARE_DT	SOC date (This is a key field only on SOC assessments where RFA = 01)
M0032_ROC_DT	ROC date (This is a key field only on ROC assessments where RFA = 03)
M0906_DC_TRAN_DTH_DT	Discharge, transfer, death date (This is a key field only on transfer to inpatient facility assessments where RFA = 06 or 07, death at home assessments where RFA = 08 and discharge assessments where RFA = 09)

HHAs can electronically correct key field errors in production records in addition to non-key field errors and also remove erroneous records using an automated methodology called inactivation. With the ability to inactivate erroneous OASIS assessments, as described below, HHAs will be able to remove assessments from the OASIS State System's active database that have been submitted in error. These records are not actually deleted, but are moved from the active database to a history database that contains records that have been modified or inactivated. This approach keeps an audit trail of modified and inactivated records, but "hides" them from the normal OASIS State System reporting procedures.

2202.11A - Determining When to Inactivate an Assessment

(Rev. 1, 05-21-04)

If an error has been made in one or more key fields, or if an assessment was submitted in error, the HHA should electronically inactivate it. Use of the inactivation procedure is not applicable to correcting assessments with only non-key field errors. In other words, if an assessment contains errors in only non-key fields, then correction type 3 described at C.3. below should be used. In order to determine whether to submit an inactivation request, the user should apply the following rules:

1. Assessment Submitted in Error

   If an assessment was submitted in error (i.e., it should never have been submitted), it must be inactivated. For example, if a discharge assessment was submitted by the therapist; however, the patient is still being visited by the nurse, an inactivation request must be submitted for the erroneous discharge record. Another reason to inactivate an assessment would be if the submitted assessment contained the wrong patient name.

2. Error in Key Field

   If an assessment was submitted which contained an error in any of the key fields listed above, then an inactivation request must be submitted. Normally, the HHA will also submit a new, corrected assessment in this situation. For example, if the HHA discovers that the patient's last name on the SOC assessment is spelled "Smyth," while on the Follow-up assessment it is spelled "Smith," it needs to make the appropriate correction. When the HHA determines the discrepancy, the incorrect record must be inactivated and a new corrected record must be submitted.

3. Submission of Incorrect Format

   If an assessment was erroneously submitted in a masked format, that is, it was later discovered that the patient was a Medicare or Medicaid patient but was not originally indicated as such at M0150, then an inactivation must be submitted. Normally, the HHA will also submit a new, corrected assessment in this situation. For example, if the value at M0150 for a submitted and accepted assessment is not equal to 1, 2, 3, or 4, **and it should have been**, then an inactivation request should be submitted

NOTE: There is no automatic mechanism to reactivate a record that has been inactivated. Consider the case where a discharge assessment is submitted to the OASIS State System for a patient, but is inadvertently inactivated. There is no means to "undo" the inactivation and thereby "reactivate" this discharge. Instead the HHA must submit the discharge record again. An inactivated record can only be "undone" by the re-submission of the record.

2202.11B - Deleting Assessments

(Rev. 1, 05-21-04)

In certain infrequent situations, inactivation is not sufficient to correct assessment errors since inactivation alone does not remove the assessment record from the OASIS State System. Two situations require deletion of an erroneous assessment, rather than inactivation. States will continue to need to submit deletion requests on behalf of HHAs, upon request, to IFMC when the following situations occur.

1. Assessment Deletion

The HHA submits identifiable data on patients not defined by the OASIS system of records. The OASIS repository is limited to the collection of identifiable data on patients who are Medicare and/or Medicaid patients receiving skilled care with certain exceptions, i.e., under 18 and maternity patients. In instances where the OASIS State System has received OASIS data on patients not included as part of the OASIS System of Records, the data needs to be deleted.

EXAMPLE: The HHA checks Response 1, 2, 3, and/or 4 in the Current Payment Source (M0150 field) for that assessment record **and it should not have**. The record is transmitted to the OASIS State System and accepted. The HHA determines that the response for M0150 is in error. The patient was not a Medicare or Medicaid patient; therefore, this data should not be stored on the State's database.

EXAMPLE: The HHA submits an incorrect birth date on a patient who is a year old, which was accepted because the birth year identified the patient as being over 18. The patient was actually under 18 and the assessment should be deleted.

The HHA must send the following information in writing to the State OASIS coordinator to request deletion of an assessment:

- HHA Name;
- HHA ID;
- Patient ID;
- Patient Name (First and Last);
- SSN;
- RFA type;
- Effective Date;*

- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The State will then send in writing to IFMC the following information to request deletion of an assessment:

- HHA_AGENCY_ID;
- M0020_PAT_ID;
- M0040_PAT_FNAME;
- M0040_PAT_LNAME;
- M0064_SSN;
- M0100_ASSMT_REASON;
- Effective Date;*
- Submission Date/time;
- Submission Batch Id;
- Assessment Internal Id; and
- Reason this data should be removed from the State's database.

*Effective dates are:

M0030_START_CARE_DT for RFA types 01;

M0032_ROC_DT for RFA type 03;

M0090_INFO_COMPLETED_DT for RFA types 04 & 05; and

M0906_DC_TRAN_DTH_DT for RFA types 06, 07, 08, & 09.

2. File Deletion

The HHA submits a file as "Production" data instead of "Test" data. The State must verify the HHA's claim of "Production" data versus "Test" data. The HHA must

send the following information in writing to the State coordinator to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The State will then send in writing to IFMC the following information to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.
- The following events will then take place:

IFMC will create a report from the above listed information. This report will be sent to the State OASIS Coordinator for him/her to verify the accuracy of assessment(s) to be deleted from the State's database.

- The OASIS Coordinator will notify IFMC that the information is accurate and should be deleted from the State's database.
- IFMC will consult with CMS on any questionable deletion requests.
- IFMC will delete the data upon approval from CMS.
- IFMC will keep a log of all deleted data from each State's database.

The deletion request information should be communicated to IFMC by one of the following methods:

- Faxing the requested information to 1-888-477-7871; or

- Mailing the information to: IFMC
  6000 Westown Parkway
  Suite 350E
  Des Moines, IA 50266-7771.

NOTE: This information MUST NOT be sent via e-mail due to the confidentiality of the information.

States may use the worksheets available in QTSO Memorandum 2001-043 (available on the QTSO Web site) to effectuate deletion requests or devise their own, as long as all the necessary information is captured. The deletion request sheets must be submitted to IFMC by the State. Requests received directly from HHA will not be accepted.

2202.11C - Types of Corrections an HHA Can Make in HAVEN

(Rev. 1, 05-21-04)

HAVEN offers the following menu of corrections an HHA can make:

1. Assessment was Submitted to the State and was Rejected

   The HHA can unlock the assessment (the lock date changes to reflect the date the correction was made), make the necessary changes, re-lock the assessment, and re-submit it. Because of the built-in edit checks, HHAs using the HAVEN software should not expect records to be rejected by the OASIS State System for this reason. Note that the following examples are provided for illustration purposes to troubleshoot HAVEN-like software, but cannot occur in HAVEN.

   EXAMPLE 1: The HHA Agency ID field in one or more assessment records does not match the HHA Agency ID in the header record of the submission file. The entire submission file is rejected and no data is loaded into the state database.

   EXAMPLE 2: The patient's last name was missing from the assessment file (data record). The HHA may have inadvertently left this field blank. The OASIS State System must have the patient's last name. The data record in this example would be rejected and no data from this record would be loaded into the state database.

   In these examples, the HHA would make the necessary corrections and re-submit the record. Since the OASIS State System never accepted the original assessment, the correction number field IS NOT incremented in this situation. HHAs may still receive a warning if submission/timing guidelines have been exceeded.

2. Assessment was Submitted to the State and was Accepted. Correction to Key Fields is Necessary

With the implementation of the OASIS State System update, this option will display in HAVEN but will no longer be available and is disabled in the HAVEN software. To correct an assessment with key field errors, first inactivate the assessment, then create a new assessment for re-submission, as applicable. See correction type 4 below.

3. Assessment was Submitted to the State and was Accepted. Correction to Non-Key Fields is Necessary

If an HHA determines that a correction(s) must be made to non-key fields only (i.e., any fields in the OASIS data set not contained in the key fields listed above), the HHA should re-open the assessment, revise the targeted non-key fields, and re-lock and re-submit the corrected record. The lock date changes to reflect the date the correction was made.

NOTE: "CORRECTION_NUM" is a counter field contained in the programming of the HAVEN software used to track corrections made to an assessment record. The counter field is set to 00 when an assessment record is initially locked. The counter field is incremented in this case. Both the original assessment and the corrected assessment will be stored in the state database. When this type of correction occurs, the rule requiring the lock date to be within 7 days of the assessment's completion date (M0900) is waived for the corrected record.

4. Assessment was Submitted to the State and was Accepted. Inactivation of the Assessment is Necessary

This is an option in HAVEN that allows HHAs to correct key field errors by inactivating the assessment(s) containing key field errors and re-submitting a new, corrected assessment. Unlike making non-key field changes, as described in correction type 3 above, the HHA does not simply unlock the assessment record, make the necessary key field changes, re-lock the record, and re-submit it. Instead, the HHA is taken directly to the assessment in question where it can be viewed in a read-only format. While in read-only mode, when the HHA confirms that the assessment should be inactivated, HAVEN will ask the HHA to commit to this selection. The correction number field on the HAVEN Management screen displays an "X" and the assessment status is set to "Locked (Export Ready)." The "X" indicates that this assessment has been prepared for inactivation.

When the HHA selects this correction type, a copy of the original assessment record is created. To re-submit the assessment with the necessary corrections, the HHA first exports the assessment that is being inactivated. From the HAVEN Management screen, the HHA then selects the inactivated record in question and clicks on the "Correct Assessment" button. A pop-up box will appear asking if the HHA wants to make any corrections to this assessment. When the HHA clicks on the "OK" button, a copy of the original assessment appears. The HHA makes the necessary changes

and re-submits the assessment. The correction number for this assessment is reset to 00. The lock date changes to reflect the date the correction was made.

2202.11D - Documentation of Corrected Assessments

(Rev. 1, 05-21-04)

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record in accordance with current clinical record requirements at 42 CFR 484. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the clinical record requirements at 42 CFR 484.

2202.11E - Clinical Implications of Corrected Assessment Records

(Rev. 1, 05-21-04)

When corrections are made to an assessment already submitted to the OASIS State System, the HHA must determine if there is an impact on the patient's current care plan. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current care plan. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment (CMS Form-485), or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.

2202.11F - Regarding Corrections in Lieu of Required Assessments

(Rev. 1, 05-21-04)

Collection and submission of information on SOC, ROC, Follow-up, Other Follow-up, transfer, and discharge assessments are required by the comprehensive assessment requirements at 42 CFR 484. The correction process described here does not preclude the need for accurate patient assessment at the required time points.

The inactivation of an assessment and subsequent correction and re-submission of a new assessment, or a correction to a non-key field cannot be used in lieu of the appropriate OASIS assessment for documenting an unanticipated change in patient condition that was not envisioned in the original plan of care. If there is an unexpected change in the patient's clinical condition due to a major decline or improvement in health status that warrants a change in plan of treatment, the appropriate OASIS assessment is expected to document the change, i.e., the ROC or Other Follow-up assessment, as appropriate. This is in keeping with the regulation at 42 CFR 484.20(b) for accuracy of encoded OASIS

data that states, “The encoded OASIS data must accurately reflect the patient’s status at the time of assessment.” The HHA should have one document for the patient’s assessment, care planning, and payment purposes.

2202.11G - Timeliness of Corrections

(Rev. 1, 05-21-04)

Currently there are no requirements regarding the timeliness of correcting and inactivating assessment records, either in terms of when they must be completed (locked) or submitted. However, HHAs are urged to make corrections and/or submit inactivations as quickly as possible after errors are identified so the state system will be as current and accurate as possible. This affects the data used to calculate the HHA’s OBQI and OBQM reports.

2202.11H - Multiple Corrections in a Record

(Rev. 1, 05-21-04)

Correcting assessments with key field errors can only be done by inactivating the incorrect assessments and replacing them with the corrected assessments, as previously described above. Correcting assessments with non-key field errors can only be done by re-opening the assessment, revising the targeted non-key fields, re-locking and re-submitting the assessment, as previously described above. “CORRECTION_NUM” (the counter field) is implemented in non-key field changes. For more specific information concerning the process of correction and inactivation, refer to the OASIS data specification notes on the OASIS web site.

See below for a flow chart depicting the most common situations necessitating corrections

2202.12 - OASIS State System

(Rev. 1, 05-21-04)

The purpose of the OASIS State System is to provide computerized storage, access, and analysis of the OASIS data on patients in HHAs across the nation. The OASIS State System is intended to create a standard, nationwide system for connecting HHAs to their respective SAs for the purpose of electronic interchange of data, reports, and other information. The automated OASIS system is a critical component of SA and CMS operations. It is a key part of a fully integrated system of clinical data, facility demographics, survey findings, and SA operations information. The OASIS State System also provides the means for transmission of assessment data to CMS for validating payments under prospective payment for HHAs.

The OASIS State System implementation involved a CMS-funded installation of standardized computer hardware and data management software at each SA to allow electronic transfer of OASIS data elements from all HHAs to the State. The data management software:

- Validates the basic accuracy of the data and rejects submission files (batches) with fatal file errors, such as a missing or invalid agency ID, incorrect record length, or missing headers or trailers;

- Validates individual assessment records and rejects those records with fatal record errors;

- Stores and reports non-fatal or warning errors on records that are accepted by the database; and

- Builds a database of OASIS information for all applicable patients of each HHA in the State.

In accordance with the regulations, HHAs will collect SOC, ROC, Follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge), and death at home OASIS data on all patients (except those under 18; those receiving maternity services; and patients receiving only housekeeping or chore services) under the care of the HHA as of July 19, 1999, as applicable. The requirements for OASIS collection, encoding, and transmission apply to all Medicare and Medicaid patients, including Medicare and Medicaid HMO/Managed Care patients (with the exception of those listed above) receiving skilled services. The applicability of the comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source, has been delayed until further notice. In addition, the collection , encoding and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is also temporarily suspended until further notice, although a system to mask their identity has been developed and incorporated into current versions of HAVEN. Until collection and submission of non-Medicare/non-Medicaid patient assessments is required, HHAs must meet all other requirements of the comprehensive assessment regulation including conducting SOC comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services, although the OASIS data items are not required. This means that only the requirement to collect, encode and transmit OASIS data is delayed. The collection of the comprehensive assessment and updates at the required time points is required in order to ensure quality of care for all patients and to encourage the use of OASIS as the basis for care planning.

Effective August 24, 1999, and at least monthly thereafter, HHAs should transmit to the SA all applicable OASIS data collected and encoded from July 19, 1999, and monthly thereafter. Monthly transmissions should include all OASIS data encoded and locked in the previous month.

OASIS activities will provide enhanced analytical capabilities at the SAs; electronic transmission from the State databases to a national repository; integration with performance indicators for quality oversight and survey planning by the SA; a basis for maintaining prospective payment of HHAs; research directed at improving quality of care; feedback to providers; and dissemination of information to purchasers, beneficiaries, and others.

2202.12A - System Description

(Rev. 1, 05-21-04)

The CMS has provided each State with an OASIS State System composed of standardized hardware and software platforms scaled to meet each State's anticipated processing volumes, and a standardized operating system. The hardware is comprised of a communications server, database server, the local area network, and other peripheral devices.

The OASIS State System deployed to each State was specifically engineered and purchased to fulfill the OASIS requirements of 42 CFR parts 484 and 488, additional CMS provider assessment processes as they become effective, and operational support of Medicare and Medicaid Survey and Certification pursuant to §1864 of the Act. The system was designed with an emphasis on flexibility and integration, so that additional software components could be easily added to provide the States with new related functionality (such as outcome measures and expanded analytical reports), as well as applications that support future assessment processes for other provider types, and new capabilities to support survey and certification operations. Since each State's OASIS system was specifically sized to accommodate these planned functions, the SA should not add other non-CMS prescribed applications or databases to it.

2202.12B - Administration Requirements

(Rev. 1, 05-21-04)

The OASIS State System in each State is part of a comprehensive, Quality Improvement and Evaluation System that will not only fulfill OASIS administration requirements, but also grow to support other assessment-based programs; quality and performance indicators; and new, integrated survey and certification data systems. The State should use the OASIS State System for editing, storing, and processing OASIS data to support CMS' OASIS operating requirements within the State and to transmit the required OASIS data to the CMS OASIS repository. As noted above, the State may not add additional software applications to the OASIS system without a specific directive from CMS.

The States are directly responsible for fulfilling requirements to operate the OASIS State System. However, the State may enter into an agreement with the State Medicaid

agency, another State component, or a private contractor to perform day-to-day operations of the system.

The State must obtain RO approval prior to entering into an agreement with another agency**.** Such agreements should address the following provisions:

1. Meets confidentiality requirements: Federal Privacy Act, 5 U.S.C. §522a; HIAA of 1996; other applicable Federal data acts; §1902(a)(7) of the Act; applicable State standards; and industry security standards;

2. Gives the SA real-time access to the system to fully support all OASIS-driven functions which will be required of the survey agency (e.g., quality indicator reporting, survey targeting, etc.), or if a contractor is performing analysis for SA contract, provides the details on how this is to be conducted;

3. Complies with need for high capacity, fault-tolerant network connections to ensure reliable support for the SAs, CMS' national database, and any other daily operations (e.g. Intermediary Medical Case Review, Office of the Inspector General or Department of Justice Fraud and Abuse activities), which will be affected by this system. Assures hardware will be properly maintained and upgraded as necessary to meet any future CMS or SA requirements. Assures adequate backup of all data;

4. Includes SA responsibilities for reporting OASIS data to a central repository at CMS. Designates responsibilities for edits and "cleanness" of data:

    - Designates responsibilities for generating and communicating facility error reports.

    - Describes what kinds of communication will be established, e.g., a State-specific Internet and/or Intranet web pages, newsletters, etc., their content, and who will produce/maintain/distribute these communications.

    If there is a separate database, designates who is responsible for operating and maintaining the CMS-provided equipment and who will assure the viability of the CMS database;

5. Lists responsibilities of contractor and/or State for training and support operations: Includes at least who will provide facility and OASIS software vendor startup training, and on-going customer/facility support/troubleshooting; provide internal training and daily user support within the SA; work with program staff to integrate the OASIS system into SA functions; train SA staff on aspects of analytical system (e.g., ASPEN upgrades and "performance measure/quality indicator" linked reports); handle System Operations - functions associated with transmission logging, error tracking and resolution, system archival, and process

reporting; and designate who is responsible for determining facility transmission schedules;

6. Delineates how State will fund the monthly line charges associated with installation, maintenance, and transmission of the OASIS data from the facilities to the contractor and between the contractor and State, e.g., built into contract costs or is an outside ongoing cost to the SA; and

7. Specifies whether it is the contractor's or the SA's responsibility for systems maintenance for commercial "off-the-shelf" OASIS hardware and software components.

NOTE: Standardized OASIS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS.

Under any such arrangement, the State must be guaranteed real-time, priority access to this system to fully support all OASIS functions. All CMS privacy and confidentiality requirements must be met. Off-site operation of the OASIS State System will require high capacity, fault-tolerant network connections to ensure reliable support for the State's daily operations that will be affected by this system. The State also must use the OASIS State System for reporting OASIS data to the CMS central repository.

To promote national consistency in OASIS system operations and troubleshooting, each State should designate one individual as the OASIS automation project coordinator. This person is CMS' key contact within each State for managing OASIS State System issues and must be familiar with the use of the OASIS automation and transmission process. Technical knowledge of information systems is useful but far less critical than an understanding of the OASIS processes, good communication and project management skills, and the ability to educate and work with providers and vendors to ensure successful implementation of an automated process for all providers. The State should designate additional staff, including a System Administrator, to manage the technical aspects of running the OASIS State System and support staff to assist in processing corrections, answering routine user questions, assigning passwords, etc.

With respect to systems maintenance, the OASIS State System installed in each State is comprised of commercial, off-the-shelf hardware, and software components that are generally covered under typical umbrella service agreements that the State may already have in place for maintenance of data processing equipment. Those OASIS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS. The State will not be responsible for these software upgrades.

To the extent that the State has developed customized external applications for using information obtained from the OASIS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the survey and certification budget.

2202.12C - Validation and Editing Process

(Rev. 1, 05-21-04)

Each time an HHA accesses the OASIS State System and transmits an assessment file, it performs a series of three levels of validations:

1. Fatal File Errors

   The first check examines the basic structure and integrity of the submission file. If there are fatal flaws in the file (batch of records), then the entire file is rejected and the HHA is notified of the reason for rejection in the "Initial Feedback Report." In the event that a batch is rejected due to fatal file errors, the HHA will not receive a "Final Validation Report." Fatal file errors are listed in the data specifications, which can be found on the OASIS Web site. Rejected files must be corrected and retransmitted.

2. Fatal Record Errors

   If the file structure is acceptable, then each record in the file is examined individually for fatal record errors. These errors may cause an individual assessment within a submission to be rejected. Assessments that have fatal records are not stored in the database. The HHA is informed of fatal record errors on both the "Initial Feedback Report" and the "Final Validation Report." OASIS data specifications outline the valid data requirements and are posted on the OASIS Web site.

   The Initial Feedback and Final Validation reports are available shortly following the submission of a file.

3. Non-Fatal or Warning Errors

   If there are no fatal record errors, the record is loaded into the State database and the record is further examined for non-fatal errors. Any non-fatal errors are reported to the facility in the "Final Validation Report." Non-fatal errors include missing or questionable data of a non-critical nature, record sequencing, field consistency errors, invalid value, and range errors.

The Initial Feedback Report is available immediately following the submission of a file. The HHA should obtain this report before logging off because it is not stored by the system. Since the Final Validation Report is not available for up to 48 hours after the Initial Feedback Report, the HHA may, based on experience, choose to obtain this report on a subsequent log on.

The validations and edits described above fulfill all of CMS' editing requirements under 42 CFR 488.68. Also, States may not modify any aspect of the CMS OASIS standard system, including these validations and edits, the Standard Record Layout, and the software code and specifications on which the system is based.

States that use OASIS data for Medicaid payment may require additional assessment information not required by CMS' OASIS system. Some States may impose additional edits on Medicaid assessments. However, a State may not interfere with, modify, or delay the transmission of records meeting CMS edit standards from a Medicare-certified or Medicaid-approved agency to the CMS OASIS standard system. Furthermore, the State may not impose any requirements that modify the clinical accuracy of CMS prescribed OASIS records, reports, or calculations.

2202.12D - Reports

(Rev. 1, 05-21-04)

The OASIS State System provides reports to both the State and the provider. These reports, which focus on errors in OASIS submissions, are particularly key to working with agencies to ensure successful transmission of OASIS data. Refer to the State OASIS Administration Manual available on the QTSO Web site (http://www.qtso.com/) for information about specific reports provided.

2202.12E - Replication to the CMS Repository

(Rev. 1, 05-21-04)

Each State's OASIS database will be transmitted to CMS' central repository at least monthly using a data replication process initiated by CMS. Since the process will be managed by CMS through an automatic polling process, the States will not actually have to transmit the data. However, the State must ensure that the CMS data line established for this purpose is accessible to CMS at all times for testing and monitoring purposes. Actual access to the Oracle assessment data tables may be controlled by the States but in such cases, we recommend that a fixed schedule be established with CMS central office.

The OASIS State System and CMS data line meet all industry security standards. However, if the State is concerned about security, it may establish a firewall (an electronic block) to restrict access to the State's portion of the network. Access must not be restricted to the CMS-supplied OASIS System.

2202.12F - System Security

(Rev. 1, 05-21-04)

As distinguished from confidentiality and privacy, which primarily focuses on the rules for release of information when it is authorized, security relates to the means by which

the information is protected from "unauthorized" access, disclosure, and misuse. As part of the new requirements under 42 CFR 488.68, States must ensure that electronic data in the OASIS State System are protected to the same degree that paper records containing any identifiable data must be safeguarded. Additionally, any printed copies of reports from the system must be maintained in a secure locked area while they are needed and properly disposed of when no longer needed. States must issue a policy that defines and limits the qualifications for an individual to access the OASIS State System. The System Administrator must issue passwords and user IDs in strict adherence to those requirements. State personnel who receive passwords must be aware of the requirements of the State's security policies and those of the System of Records and the Privacy Act. Passwords must be protected by the System Administrator and those receiving passwords. Passwords must be disabled at the time an individual exits a position requiring OASIS State System access. SAs are likewise reminded of the secure nature of passwords for the HHAs and must use due process to ensure the security of those passwords.

State personnel should not leave the OASIS State System in a logged-in status when leaving the area. If possible, the system hardware should be located in an enclosed area, preferably with a door having interior hinges that can be locked. Keys or a combination lock should be available to only a minimum group of individuals with need for access to the system.

In addition to the specific guidance above, the safeguards must provide a level of security at least equivalent to that required by the Office of Management and Budget Circular A-130 (revised), Appendix III, Security of Federal Automated Information Resources.

2202.12G - Security of Transmission

(Rev. 1, 05-21-04)

OASIS data is encoded and transmitted from HHAs to SAs via the MDCN, a private communications network CMS purchased to ensure the security of OASIS and MDS transmissions to the State. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. Standard industry authentication is employed at each SA. Further security is provided at the SA by isolation of the receiving communications server from the actual storage site at the State (the MDS/OASIS Database Server). This serves effectively as a security firewall. Transmission of OASIS data from the SAs to CMS occurs via CMS' Virtual Private Network (VPN), which allows only authorized CMS staff access within this secure CMS infrastructure.

The CMS has determined that the transmission of OASIS data through the process described above is fully compliant with all current Federal, Department of Health and Human Services, and CMS information system's security requirements. The applicable Federal guidelines include The Computer Security Act of 1987, Federal Information Processing Standards promulgated by the National Institute of Standards and Technology

pursuant to the Computer Security Act of 1987, the Office of Management and Budget Circular A-130 (revised), and Appendix III, Security of Federal Automated Information Resources.

2202.12H - Provider Relations

(Rev. 1, 05-21-04)

With CMS technical support and guidance, the States work closely with the provider community and their OASIS software vendors in providing information on specific requirements related to the submission of OASIS assessments to the OASIS State System.

The CMS expects that some vendors will provide primary support to HHAs in terms of OASIS encoding and transmission to the State repository. The State, however, must work with HHAs and software vendors in educating them about this process. The States must also provide training and technical assistance in interpretation of OASIS reports provided to HHAs.

2202.13 - Protection of the Confidentiality of OASIS Data

(Rev. 1, 05-21-04)

2202.13A - OASIS System of Records

(Rev. 1, 05-21-04)

The OASIS database is operated and maintained by States or CMS contractors as a Federal database and, as such, is subject to the requirements of the Federal Privacy Act. In general, the only records subject to the Privacy Act are records that are maintained in a system of records (SOR). The idea of a "system of records" is unique to the Privacy Act and requires explanation.

The Act defines a "record" to include most personal information maintained by an agency about an individual. A record contains individually identifiable information, including but not limited to information about education, financial transactions, medical history, criminal history, or employment history. A SOR is a group of records from which information is actually retrieved by name, social security number, or other identifying symbol assigned to an individual.

The text of the SOR notice for the OASIS database describes the legal requirements regarding privacy and disclosure of information by CMS or the State. The name of the system is HHA OASIS, (System No. 09-70-9002).

The CMS established a new SOR, published June 18, 1999, in the "Federal Register" (64 FR 32992) containing data on the physical, mental, functional, and psychosocial status of

patients receiving the services of HHAs that are approved to participate in the Medicare and/or Medicaid programs. The purpose of the system is to aid in the administration of the survey and certification of Medicare/Medicaid HHAs and to study the effectiveness and quality of care given by those agencies. This system also supports regulatory, reimbursement, policy, and research functions, and enables CMS to provide HHAs with outcome data for providers' internal quality improvement activities.

The OASIS SOR was modified and published on December 27, 2001, (66 FR 66903) to allow a new routine use authorizing disclosure to national accrediting organizations that have been approved by CMS for deeming authority for Medicare requirements for home health services. This SOR notice replaces the SOR notice published June 18, 1999.

The HHA SOR contains individually identifiable clinical assessment information (OASIS records) for all Medicare/Medicaid patients receiving the services of a Medicare and/or Medicaid approved HHA, except prepartum and postpartum patients; patients under 18 years of age; patients receiving only housekeeping services and/or chore services exclusively; and, until sometime in the future, patients receiving only personal care services. The CMS established the system in accordance with the principles and requirements of the Privacy Act.

2202.13B - Protection of Confidentiality Under the Privacy Act of 1974

(Rev. 1, 05-21-04)

OASIS data are generally protected under the provisions of the Privacy Act of 1974. The Privacy Act of 1974 protects the confidentiality of person-specific records that are maintained by the Federal Government and retrieved by a unique indicator. It contains 12 conditions of disclosure under which these records may be released without the written consent of the individual.

The system notice for the OASIS repository (HHA OASIS) was originally published in the "Federal Register" on June 18, 1999, and modified on December 27, 2001. The system notice contains a listing of the prescribed limited circumstances under which person-specific records contained in that system may be released. These circumstances are called routine uses. Routine uses must be compatible with the purpose for which the records are collected and maintained. The OASIS system notice now contains nine routine uses.

Requests submitted to CMS for release of OASIS data are forwarded to the appropriate data release authority. The authority to release data from the OASIS national repository is limited to the System Manager and his or her designees. The OASIS System Manager is the Director of the Center for Medicaid and State Operations, CMS, and as such has the sole authority to grant or deny a request for access to, or disclosure of data contained in the HHA OASIS system of records. It is the responsibility of the data release authority to review these requests for adherence to Privacy Act requirements. Release of data from any system is discretionary.

Release of data from the OASIS repository follows CMS policy and procedure for data release. It is CMS policy that each requestor of Privacy Act protected data must sign a CMS approved Data Use Agreement (DUA). A DUA is not required by the Privacy Act, however; it is one safeguard CMS has instituted in order to protect the confidentiality of identifiable data. DUAs are an integral part of the data use approval process. The agreements delineate the confidentiality requirements of the Privacy Act and CMS' data use policies. The agreement serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the agreements serve as a control mechanism through which CMS can track the location of its data and the reason for the release of the data. CMS' Office of Information Systems carries the functional responsibility to control guidelines and policies for the language in the agreements and coordinates the requests for release of data.

2202.14 - SA and RO Roles and Responsibilities

(Rev. 1, 05-21-04)

2202.14A - State

(Rev. 1, 05-21-04)

The CMS expects the SA to play a key role in providing the educational and technical resources to HHAs in each State concerning OASIS. States must designate an OASIS Automation Coordinator and OASIS Educational Coordinator to function as resources for the HHAs in each State. These positions are funded by CMS through the Medicare Survey and Certification program.

Each State Automation Coordinator must have the ability, through education, training, or experience, to provide for the statewide administration of the OASIS project. The State Automation Coordinator provides systems operations and technical support for the HHAs, vendors, and SA staff. The State OASIS Educational Coordinator must be a member of any professional discipline operating in the home health environment, that is, a social worker, registered nurse, occupational therapist, or physical therapist. Together, the functions of these two positions include providing training and educational support to HHAs in the administration of OASIS for:

- Integrating the OASIS items into the HHA assessment process;
- Answering questions on the clinical aspects of OASIS;
- Training HHAs on the OASIS data set administration;
- Providing information about hardware and software requirements for HHAs to consider when automating OASIS;

- Training HHAs on submission of OASIS data to the State and interpreting validation reports, including providing support for transmission of test data during start-up, supporting callers requesting technical assistance, providing passwords to HHAs, and answering questions about computer edits and reports;

- Submit an annual training report of the state-wide OASIS training and other activities in the Home Health Training Worksheet available in Casper reports of the QIES system by October 15 following each Federal Fiscal Year.

- Using the outcome reports generated by the OASIS data;

- Using OASIS data in survey tasks;

- Training other SA staff, as applicable;

- Providing information from OASIS to determine prospective payment rates for HHA patients; and

- Participating in training updates on OASIS and related home health issues.

2202.14B - Regional Office

(Rev. 1, 05-21-04)

ROs also have educational and automation coordinators for the implementation and automation of OASIS. Designated RO staff provide information about OASIS in the region, answer OASIS-related questions, administer survey and certification funds, and administer other aspects of the OASIS project. At least one RO staff person, knowledgeable about home health survey and certification issues, and/or knowledgeable about MDS automation coordination should be assigned to these OASIS related roles. ROs must provide the States with the program guidance and technical assistance critical to the successful implementation of OASIS and ensure that the States have the necessary resources to accomplish these goals.

The following activities are performed by the RO:

1. Budget Process

   The RO reviews each SA's budget request and the required OASIS Implementation Plans in accordance with the Budget Call Memorandum. The RO must monitor for a reasonable and prudent expenditure of funds to ensure that States receive a fair and reasonable allocation. The RO must monitor Quarterly Expenditure Reports against the States' allocation.

2. Review State Implementation Plans

   The RO annually reviews all State OASIS Implementation Plans to ensure States have reasonable plans for assisting HHAs with the technical information, training, and assistance needed to comply with requirements for OASIS submission, accuracy, privacy, and security. The RO must assess whether States are monitoring HHA compliance with the OASIS requirements.

3. Review Contracts and Agreements

   The RO ensures that the SA has executed an agreement with any other entity if that other entity is operating the OASIS system on behalf of the SA. The RO must use the criteria in §2202.12.B in performing this review.

4. Provide Training and Technical Assistance

   The RO provides training and technical assistance to the States in OASIS implementation requirements and provides continuing education about the OASIS program.

5. Perform Focused Reviews/Federal Surveys

   The RO uses the OASIS Repository and outcome data to select HHAs for focused reviews, and in preparation for Federal surveys.

6. Take Enforcement Action.

   The RO processes and carries out enforcement actions for non-compliance with OASIS requirements (as reported by SAs).

2202.15 - OASIS Education and Training

(Rev. 1, 05-21-04)

2202.15A - State

(Rev. 1, 05-21-04)

The OASIS Educational and Automation Coordinators participate in various training programs concerning OASIS, monthly teleconferences to discuss OASIS implementation issues, and meetings for OASIS updates and other matters related to home health services, as necessary. State support is provided by CMS central office, ROs, the OASIS Web site, and clinical and technical Help Desks supported by CMS contractors.

2202.15B - RO

(Rev. 1, 05-21-04)

The RO OASIS Coordinators participate in regularly scheduled teleconferences with central office to discuss issues concerning implementing and maintaining OASIS and other related survey issues. RO staff participate in periodic meetings for OASIS updates and other matters related to home health services as scheduled.

2202.15C - HHAs

(Rev. 1, 05-21-04)

All HHAs, both existing and prospective, are trained on the implementation and automation of OASIS by each State's OASIS Educational and Automation Coordinators. HHAs with clinical, technical and regulations-related questions should contact the State OASIS Educational or Automation Coordinator about OASIS. A current list of the State OASIS Educational Coordinators is found on the OASIS Web site. Support is also available for HHAs via the OASIS Help Desk. The Help Desk can be accessed toll-free by telephone on (877) 201-4721 between the hours of 7 a.m. and 7 p.m. Central Time and by electronic mail at HAVEN_help@IMFC.org.

The SA provides support to HHAs by providing OASIS presentations at meetings sponsored by the SA, HHA provider associations, or other entities.

Updates to existing software and training manuals which support OASIS implementation, HAVEN, and the OASIS State System, are distributed via the OASIS Web site.

2202.16 - Fax Transmission of OASIS or Other Patient Identifiable Information

(Rev. 1, 05-21-04)

The use of electronic means of communication is acceptable in HHAs, if appropriate safeguards are in place. The fax machine provides a fast and inexpensive method to send and receive patient specific information, such as patient referrals and physician orders. However, the use of fax transmission can open up the possibility that confidential patient information can be transmitted or handled in a manner that is not secure and does not protect the patient's confidential health information. For example, the use of an incorrect fax number can allow the material being transmitted to persons who are not legally authorized to have this information. Inasmuch as the CMS takes its responsibility seriously to protect patient specific information once it has been transmitted to the State, we expect HHAs to provide the same protections to OASIS data while it is maintained at the HHA.

The home health CoP at 42 CFR 484.11, Release of Patient Identifiable OASIS information, requires that HHAs and agents acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable information to the public.

It is the responsibility of the HHA to make sure that it has a written contract providing its agent with the legal authority to encode and transmit OASIS assessment data. The contract should also ensure that the agent holds all OASIS data confidential. Each HHA that uses fax transmission of OASIS information should develop its own policies and procedures to assure confidentiality of patient information, as well as, comply with legal, regulatory and accreditation requirements. It is also the responsibility of the HHA to make sure that OASIS assessment data is transmitted to its agent by a secure method.

If the HHA chooses to use facsimile transmission of OASIS data, guidelines for use of facsimile transmission of OASIS data are provided below:

- The HHA or agent should place fax machines in a secure area and limit access to them.

- The HHA should identify one person in a department or unit to monitor incoming documents on a fax machine, or to deliver the document information directly into a secured data base system.

- The HHA should outline appropriate written policies that safeguard that transmitted OASIS information is sent to the appropriate person and verify the correct facsimile number to which the OASIS data is being transmitted. This should include:

    (a) Use of the of a cover sheet, either electronic or hard copy, accompanying the faxed information that specifies that the OASIS information is confidential and limits its use to the terms of the written contract;

    (b) That the person who is the legal authority for the receipt of the OASIS information is prohibited from disclosing this information to any other party, any may use the data only for the purposes outlined in the written contract; and

    (c) The HHA should contact the agent to verify the correct fax number to use prior to faxing.

The HHA should develop and enforce procedures to be followed in the case of a misdirected transmission. This should include:

(a) A notice on the cover sheet that prohibits the disclosure, copying, or distribution of the information by the unintentional receiver of the fax,

(b) A notice to the unintentional receiver of the fax to notify the sender immediately if they have received this information in error to arrange for the return of the information, and

(c) The name and phone number of the sender to contact.

State survey agencies should follow the same guidelines outlined above when using fax machines for doing such things as sending and receiving requests to correct errors to the OASIS data base.

2202.17 - Change of Ownership, Merger, and Termination Procedures Affecting HHAs and OASIS Requirements

(Rev. 1, 05-21-04)

It is imperative that the Medicare provider number be accurately reported on the OASIS assessments in all reports, including when HHAs undergo change of ownership, merger, or termination.

Change of Ownership - Mergers

In accordance with 42 CFR Part 489.18 and §3210, the merger of a provider corporation into another corporation constitutes a change of ownership. In the case of the merger of Agency A into Agency B, Agency A's provider agreement and its associated provider number are terminated. Agency B retains its existing provider agreement and provider number. Agency A should provide the OASIS discharge comprehensive assessment for each discharged patient prior to or at the effective date of the merger. The surviving HHA (Agency B) should provide a Start of Care (SOC) comprehensive assessment for all persons it admits after the merger at the next skilled visit after the official merger date. The SOC assessment will allow eligibility for the home health benefit to be verified and care planning for the individual to proceed under Agency B. Subsequently, the assessments for all individuals being accepted for care by Agency B will be linked to the correct provider number to enable the agency to engage in quality improvement efforts with accurate OBQI reports.

In accordance with 42 CFR Part 489.18 and §3210, when there is a change in ownership and the new owner accepts assignment of the existing provider agreement, the new owner is subject to all the terms and conditions under which the existing agreement was issued, including compliance with the comprehensive assessment of patients condition of participation. The provider number remains the same if the new HHA owner accepts assignment of the existing provider agreement. The new owner is responsible for continuing to complete updates to the comprehensive assessment at the next scheduled time points.

Change of Ownership without Assignment

In accordance with 42 CFR Part 489.18 and §3210, when there is change of ownership and the new owner rejects this assignment of the provider agreement, the provider agreement and provider number of the former owner should be terminated.
The HHA that is terminating its provider agreement and provider number should provide an OASIS discharge comprehensive assessment for each patient subject to OASIS standards prior to the effective date of the termination, according to 42 CFR 484. The new HHA will not be able to participate in the Medicare program without going through the same process as any new provider, which includes an initial survey. The HHA should meet all the Federal requirements, including applicable OASIS requirements as specified in the regulations, for all persons it accepts for care in order to participate in the Medicare program. This means that the HHA should provide a new SOC comprehensive assessment at the first skilled visit once it becomes Medicare-approved. In addition, updates to the comprehensive assessment should be provided at the other OASIS time points, in accordance with 42 CFR Part 484, for all patients of the former owner it accepts for care.

Voluntary Terminations

In accordance with 42 CFR Part 489.52 and §3046, a Medicare approved HHA may voluntarily terminate its provider agreement by filing a written notice of its intention to the State Agency who, in turn, notifies the RO. CMS recommends the HHA that is terminating its provider agreement should provide a discharge comprehensive assessment for each patient prior to the effective date of the termination.

Involuntary Terminations

The RO may terminate an agreement with an HHA, in accordance with 42 CFR 489.53. CMS will work with the HHA on a case-by-case basis to provide for the safe and orderly transfer of patients to another Medicare-approved HHA if appropriate.

2202.18 - Wound Ostomy Continence Nurses Society (WOCN) OASIS Guidance

(Rev. 1, 05-21-04)

The CMS collaborated with clinical wound care experts from the WOCN to clarify the definitions for “fully granulating, early/partial granulation, and not healing” for OASIS wound items. The clarifications are intended to be helpful to home health agency (HHA) clinicians as they complete their patient assessments. For more information about the WOCN guidelines and for answers to questions about the WOCN guidelines, please contact the WOCN web site at www.wocn.org.

HHA clinicians are encouraged to use the WOCN guidance to assist with clinical assessments of patient wounds. The WOCN OASIS Guidance follows:

Overview and Background

Home Health Reimbursement shifted to a prospective payment system effective October 2000. Under this system, payment is based on the patient's clinical severity, functional status, and therapy requirements. The system for wound classification uses terms such as "nonhealing," "partially granulating," and "fully granulating"; these terms lack universal definition and clinicians have verbalized concerns that they may be interpreting these terms incorrectly. The WOCN Society has therefore developed the following guidelines for classification of wounds. These items were developed by consensus among the WOCN's panel of content experts.

M0 445: Does the patient have a Pressure Ulcer?

M0 450 Current number of Pressure Ulcers at Each Stage

M0 460 Stage of Most Problematic (Observable) Pressure Ulcer

Stage I

Stage II

Stage III

Stage IV

NANo observable pressure ulcer

Definitions:

Pressure Ulcer: Any lesion caused by unrelieved pressure resulting in damage of underlying tissue. Pressure ulcers are usually located over bony prominences and are staged to classify the degree of tissue damage observed.

Stage I: Non-blanchable erythema of intact skin, the heralding lesion of skin ulceration. In individuals with darker skin, discoloration of the skin, warmth, edema, induration, or hardness may also be indicators.

Stage II: Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents as an abrasion, blister, or shallow crater.

Stage III: Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV: Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g. tendon, joint capsule). Undermining and sinus tracts may also be associated with Stage IV pressure ulcers.

Non-observable: Wound is unable to be visualized due to an orthopedic device, dressing, etc. A pressure ulcer cannot be accurately staged until the deepest viable tissue layer is visible; this means that wounds covered with eschar and/or slough cannot be staged, and should be documented as non-observable.

M0 464: Status of Most Problematic (Observable) Pressure Ulcer

1 Fully granulating

2 Early/partial granulation

3 Not healing

NANo observable pressure ulcer

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: ≥ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges open.

Non-healing: Wound with ≥25% avascular tissue OR signs/symptoms of infection;

OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges;

OR persistent failure to improve despite appropriate comprehensive wound management. Note: A new Stage 1 pressure ulcer is reported on OASIS as not healing.

M0 468: Does the patient have a stasis ulcer?

M0 470: Current number of Observable Stasis Ulcer(s)

M0 474: Does this patient have at least one Stasis Ulcer that cannot be observed?

M0 476: Status of the Most Problematic (Observable) Stasis Ulcer

1 Fully granulating

2 Early/partial granulation

3 Not healing

NANo observable stasis ulcer

Definitions:

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: ≥ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges open.

Non-healing: Wound with ≥25% avascular tissue OR signs/symptoms of infection OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges OR persistent failure to improve despite appropriate comprehensive wound management.

M0 482: Does the patient have a Surgical Wound?

M0 484: Current number of (Observable) Surgical Wounds

M0 486: Does the patient have at least one Surgical Wound that cannot be observed due to the presence of a non-removable dressing?

M0 488: Status of the most problematic (Observable) Surgical Wound

1. Fully granulating

2. Early/partial granulation

3. Not healing

NANo observable surgical wound

Description/classification of wounds healing by primary intention (i.e., approximated incisions)

Fully granulating/healing: incision well-approximated with complete epithelialization of incision; no signs or symptoms of infection; healing ridge well defined

Early/partial granulation: incision well-approximated but not completely epithelialized; no signs or symptoms of infection; healing ridge palpable but poorly defined

Non-healing: incisional separation OR incisional necrosis OR signs or symptoms of infection OR no palpable healing ridge

Description/classification of wounds healing by secondary intention (i.e., healing of dehisced wound by granulation, contraction and epithelialization)

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: $\geq$ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges are open.

Non-healing: Wound with $\geq$ 25% avascular tissue OR signs/symptoms of infection OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges OR persistent failure to improve despite comprehensive appropriate wound management.

GLOSSARY

Avascular: Lacking in blood supply; synonyms are dead, devitalized, necrotic, and nonviable. Specific types include slough and eschar.

Clean Wound: Wound free of devitalized tissue, purulent drainage, foreign material or debris

Closed Wound Edges Edges of top layers of epidermis have rolled down to cover lower edge of epidermis, including basement membrane, so that epithelial cells cannot migrate from wound edges; also described as epibole. Presents clinically as sealed edge of mature epithelium; may be hard/thickened; may be discolored (e.g., yellowish, gray, or white).

Dead Space:	A defect or cavity
Dehisced/Dehiscence:	Separation of surgical incision; loss of approximation of wound edges
Epidermis:	Outermost layer of skin
Epithelialization:	Regeneration of epidermis across a wound surface
Eschar:	Black or brown necrotic, devitalized tissue; tissue can be loose or firmly adherent, hard, soft or soggy.
Full Thickness:	Tissue damage involving total loss of epidermis and dermis and extending into the subcutaneous tissue and possibly into the muscle or bone
Granulation Tissue:	The pink/red, moist tissue comprised of new blood vessels, connective tissue, fibroblasts, and inflammatory cells, which fills an open wound when it starts to heal; typically appears deep pink or red with an irregular, "berry-like" surface
Healing:	A dynamic process involving synthesis of new tissue for repair of skin and soft tissue defects.
Healing Ridge:	Palpatory finding indicative of new collagen synthesis. Palpation reveals induration beneath the skin that extends to approximately 1 cm on each side of the wound. Becomes evident between 5 and 9 days after wounding; typically persists till about 15 days post-wounding. This is an expected positive sign.
Hyperkeratosis:	Hard, white/gray tissue surrounding the wound
Infection:	The presence of bacteria or other microorganisms in sufficient quantity to damage tissue or impair healing. Wounds can be classified as infected when the wound tissue contains 10^5 (100,000) or greater microorganisms per gram of tissue. Typical signs and symptoms of infection include purulent exudate, odor, erythema, warmth, tenderness, edema, pain, fever, and elevated white cell count. However, clinical signs of infection may not be present, especially in the immunocompromised patient or the patient with poor perfusion
Necrotic Tissue:	See avascular.
Non-granulating:	Absence of granulation tissue; wound surface appears smooth as opposed to granular. For example, in a wound that is clean but

non-granulating, the wound surface appears smooth and red as opposed to berry-like.

Partial Thickness: Confined to the skin layers; damage does not penetrate below the dermis and may be limited to the epidermal layers only

Sinus Tract: Course or path of tissue destruction occurring in any direction from the surface or edge of the wound; results in dead space with potential for abscess formation. Also sometimes called "tunneling." (Can be distinguished from undermining by fact that sinus tract involves a small portion of the wound edge whereas undermining involves a significant portion of the wound edge.)

Slough: Soft moist avascular (devitalized) tissue; may be white, yellow, tan, or green; may be loose or firmly adherent

Tunneling: See sinus tract

Undermining: Area of tissue destruction extending under intact skin along the periphery of a wound; commonly seen in shear injuries. Can be distinguished from sinus tract by fact that undermining involves a significant portion of the wound edge, whereas sinus tract involves only a small portion of the wound edge.

2202.19 - OASIS Collection on Private Pay (Non-Medicare/Non-Medicaid) Patients

(Rev. 1, 05-21-04)

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 includes a provision regarding the collection of OASIS data for non-Medicare/non-Medicaid (private pay) patients. Specifically, section 704 of this Act temporarily suspends the requirement that Medicare-approved HHAs collect OASIS data on non-Medicare/non-Medicaid patients, effective December 8, 2003.